

59. (New) The method of Claim 58, wherein the at least one lysostaphin analogue is administered simultaneously with the second antimicrobial agent.

60. (New) The method of Claim 4, wherein the amount of lysostaphin analogue(s) administered is between 0.5 mg/kg/day and 200 mg/kg/day.--

REMARKS

Initially, the applicant's would like to thank Dr. Borin for the courtesies extended in granting a telephone interview on July 16, 2002.

Restriction Requirement

In the Official Action, restriction to one of the following inventions was required under 35 U.S.C. 121:

I. Claims 4, 5, 32-39, and 41-55, drawn to method of treating staphylococcal infection by systemic administration of lysostaphin; and

II. Claim 32, drawn to pharmaceutical composition of lysostaphin.

First, it should be noted that Claim 32 is not drawn to a composition but, rather, to a method. Further, Claim 32 depends from Claim 4 which claim has been categorized in Group I. It appears that Claim 28, which is drawn to a composition, was intended for inclusion in Group II of the restriction requirement and not Claim 35. This interpretation is consistent with the statement in the Official Action that Group I is considered constructively elected and that, as a result, Claim 28 is "... withdrawn from consideration as drawn to non-elected group" (See page 3 of the Official Action). In the telephone conference of July 16, 2002, Dr. Borin verified that Claim 28 (and Claim 35 which depends therefrom) was intended to be included in Group II.

Applicants respectfully traverse this restriction requirement in view of the following.

In particular, Applicants submit that examination of all of the claims in Groups I and II would not pose an undue burden on the Examiner. Section 803 of The Manual of Patent Examining Procedure states that “[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.” It is respectfully submitted that a proper search of the Invention of Group I would include a search of prior art relevant to Group II. In particular, the claims corresponding to Group II (Claims 28 and 35) are directed to a composition comprising at least one recombinantly produced lysostaphin analogue. Claims 4 and 5, which have been included in Group I, however, recite methods comprising systemically administering at least one recombinantly produced lysostaphin analogue. Accordingly, it is respectfully submitted that a proper search of the prior art relevant to Group I would also encompass prior art relevant to Group II. Applicants therefore respectfully submit that it would not pose an undue burden on the Examiner to examine all of the claims currently pending in the application.

In view of the above, the restriction is believed to be improper and Applicants respectfully request that the restriction be reconsidered and withdrawn such that the claims of Groups I and II are both examined in one application.

35 U.S.C. 103(a) Rejections

Claims 4 and 5 were rejected under 35 U.S.C. 103(a) as allegedly being obvious over Stark and Zygmunt in view of Oldham. Claims 32 and 35 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Zygmunt or Stark or Goldberg in view of Oldham as applied to claims 4 and 5 and further in view of Dixon. These rejections, which appear in paragraph 3 on pages 4-10 and in paragraph 4 on pages 10-11 of the Official Action, respectively, are respectfully traversed for the following reasons.

Claims 4 and 5 have been amended to incorporate limitations from dependent Claims 33 and 36. Claim 32 depends directly from Claim 4. Accordingly, it is respectfully submitted the above rejection is no longer applicable to Claims 4, 5 and 32. Reconsideration and withdrawal of the rejections is therefore respectfully requested.

Please note that Claim 35 depends from Claim 28 which has been withdrawn from consideration as allegedly drawn to a non-elected group (see page 3 of the Official Action). Accordingly, it is respectfully submitted that the rejection of Claim 35 is inconsistent with the position taken by the Examiner in the restriction requirement, a point which was raised in the telephone interview of July 16, 2002. Reconsideration and withdrawal of the rejection of Claim 35 is therefore also respectfully requested.

Claims 33, 34 and 36-55 were rejected under 35 U.S.C. 103(a) as being unpatentable over Zygmunt and Stark and Goldberg and Oldham. This rejection, which appears in paragraph 5 on pages 11-12 of the Official Action, is respectfully traversed for the following reasons. Claims 33, 34 and 36-39 have been canceled. Claim 40 has been canceled in a previous amendment. Claims 4, 5, 32 and 41-60 are pending.

Claim 4 recites “[a] method of treating a staphylococcal infection of at least one organ or tissue selected from the group consisting of heart valve, blood, kidney, lung, bone and meninges, comprising systemically administering to a human suffering from at least one of said infections an effective amount of at least one recombinantly produced lysostaphin analogue; wherein multiple doses per day of the lysostaphin analogue are administered in an amount of 50 mg/kg or less per dose.” Claim 5 recites “[a] method of treating a staphylococcal infection associated with a catheter or a prosthetic device, comprising systemically administering to a human suffering from such an infection an effective amount of at least one recombinantly produced lysostaphin

analogue; wherein multiple doses per day of the lysostaphin analogue are administered in an amount of 50 mg/kg or less per dose.”

It is respectfully submitted that Claims 4 and 5 are patentable over the references of record. In particular, there is no teaching or suggestion in any of the references cited in the Official Action of a method as claimed comprising systemic administration to a human of multiple doses per day of a lysostaphin analogue in an amount of 50 mg/kg or less per dose. In fact, only one of the cited references (i.e., Stark) actually discloses systemic administration to a human. In Stark, however, the patient received only a single dose of lysostaphin.

It is respectfully submitted that the Official Action has failed to establish a *prima facie* case of obviousness. First, as set forth in the MPEP, “[p]atent Examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case. The Supreme Court in Graham v. John Deere, 383 U.S. 1, 148 USPQ 459 (1966), stated:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.”

Therefore, in order to establish a *prima facie* case of obviousness, differences between the prior art and the claims at issue must be ascertained. The Official Action, however, states that “ . . . if *there are any differences between dosage ranges as claimed and that of the prior art*, the differences would be appear [sic] minor in nature.” It appears from the above statement that differences between the prior art and the claims at issue have not been ascertained as required by the Supreme Court’s holding in Graham v. John Deere.

Additionally, in order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally

available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2142. Further, as also set forth in the MPEP, “[t]he initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done. ‘To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.’ Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).” See MPEP § 2142.

According to the Official Action, “[a]bsent some teaching to the contrary, determination of particular ranges employed is within the skill of the ordinary worker as a part of the process of normal optimization.” Although it is not inventive to discover optimum or workable ranges *by routine experimentation where the general conditions of a claim are disclosed in the prior art* [See, for example, In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) and MPEP § 2144.05(II)(A)], it is respectfully submitted that the references cited in the Official Action fail to disclose the general conditions of the claimed invention. Further, it is respectfully submitted that one of ordinary skill in the art, based on the teachings of the cited references, could not have arrived at the claimed invention through routine experimentation. In particular, there is no teaching or suggestion in any of the references cited in the Official Action of a method as claimed comprising *systemic administration to a human of multiple doses per day of a lysostaphin analogue in an amount of 50 mg/kg or less per dose*.

Additionally, there is objective evidence of non-obviousness which further distinguishes the claimed invention from the references cited in the Official Action. In particular, as shown in

Table 6 of the Specification (page 21), a method of treating a staphylococcal infection as claimed resulted in a statistically significant reduction in the number of viable bacteria present in the aortas of rabbits having established endocarditis infections. Further, the experiment using a treatment within the scope of the claims resulted in complete sterilization of the heart valve vegetation in all but one (i.e., in 10 of 11) of the rabbits tested. In contrast, a separate trial employing a single daily dose of lysostaphin resulted in complete sterilization of the heart valve vegetation in only 2 of 10 rabbits tested. Further, even when lysostaphin was administered once a day in combination with vancomycin twice daily, only 3 of 11 rabbits tested showed complete sterilization of the heart valve vegetation.

According to the MPEP, objective evidence of non-obviousness must be considered whenever present. See MPEP § 716.01(a). As also set forth in the MPEP, “[e]xaminers must consider comparative data in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims. In re Margolis, 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986).” See MPEP § 716.01(a). It is respectfully submitted that the aforementioned evidence of non-obviousness presented in the specification further distinguishes the claimed invention from the references of record.

Claims 32 and 41-60 depend either directly or indirectly from Claims 4 or 5 and are therefore also patentable for at least the reasons set forth above with respect to Claims 4 and 5. Accordingly, it is respectfully requested that the rejection of Claims 32 and 41-55 be reconsidered and withdrawn.

Additionally, Claims 56 and 59 can be further distinguished from the references of record. Claims 56 and 59 depend from Claims 32 and 58, respectively, and further recite that the at least one lysostaphin analogue is administered simultaneously with a second antimicrobial agent.

There is no teaching or suggestion in any of the references cited in the Official Action of a method as set forth in Claims 56 or 59 comprising simultaneous systemic administration of Lysostaphin and a second antibiotic to a human suffering from a staph infection.

CONCLUSION

All rejections having been addressed by the present amendments and response, Applicants believe that the present case is in condition for allowance and respectfully request early notice to that effect. If any issues remain to be addressed in this matter which might be resolved by discussion, the Examiner is respectfully requested to call Applicants' undersigned counsel at the number indicated below.

Respectfully submitted,

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MARKED-UP COPY OF AMENDED CLAIMS

4. (Three Times Amended) A method of treating a staphylococcal infection of at least one organ or tissue selected from the group consisting of heart valve, blood, kidney, lung, bone and meninges, comprising systemically administering to a human suffering from at least one of said infections an effective amount of at least one recombinantly produced lysostaphin analogue;

wherein multiple doses per day of the lysostaphin analogue are administered in an amount of 50 mg/kg or less per dose.

5. (Three Times Amended) A method of treating a staphylococcal infection associated with a catheter or a prosthetic device, comprising systemically administering to a human suffering from such an infection an effective amount of at least one recombinantly produced lysostaphin analogue;

wherein multiple doses per day of the lysostaphin analogue are administered in an amount of 50 mg/kg or less per dose.

32. (Amended) The method of [claim 4 or 5] Claim 4, further comprising [wherein the lysostaphin analogue(s) is/are administered together with at least one] administering a second antimicrobial agent selected from the group consisting of a rifamycin, [or] a glycopeptide [or combination] and combinations thereof.

41. (Amended) The method of [claim 32] Claim 5, wherein the amount of lysostaphin analogue(s) administered is between 0.5 mg/kg/day and 200 mg/kg/day.

42. (Amended) The method of [claim 33] Claim 32, wherein the amount of lysostaphin analogue(s) administered is between 0.5 mg/kg/day and 200 mg/kg/day.

43. (Amended) The method of [claim 34] Claim 58, wherein the amount of lysostaphin analogue(s) administered is between 0.5 mg/kg/day and 200 mg/kg/day.

44. (Amended) The method of [claim 40] Claim 4, wherein the amount of lysostaphin analogue(s) administered is between 3 mg/kg/day and 50 mg/kg/day.

45. (Amended) The method of [claim 41] Claim 5, wherein the amount of lysostaphin analogue(s) administered is between 3 mg/kg/day and 50 mg/kg/day.

46. (Amended) The method of [claim 42] Claim 32, wherein the amount of lysostaphin analogue(s) administered is between 3 mg/kg/day and 50 mg/kg/day.

47. (Amended) The method of [claim 43] Claim 58, wherein the amount of lysostaphin analogue(s) administered is between 3 mg/kg/day and 50 mg/kg/day.

48. (Amended) The method of [claim 44] Claim 4, wherein the amount of lysostaphin analogue(s) administered is between 3 mg/kg/day and 25 mg/kg/day.

49. (Amended) The method of [claim 45] Claim 5, wherein the amount of lysostaphin analogue(s) administered is between 3 mg/kg/day and 25 mg/kg/day.

50. (Amended) The method of [claim 46] Claim 32, wherein the amount of lysostaphin analogue(s) administered is between 3 mg/kg/day and 25 mg/kg/day.

51. (Amended) The method of [claim 47] Claim 58, wherein the amount of lysostaphin analogue(s) administered is between 3 mg/kg/day and 25 mg/kg/day.

52. (Amended) The method of [claim 4 or 5] Claim 4, wherein the amount of lysostaphin analogue(s) administered is no more than 45 mg/kg/day.

53. (Amended) The method of [claim 32] Claim 5, wherein the amount of lysostaphin analogue(s) administered is no more than 45 mg/kg/day.

54. (Amended) The method of [claim 33] Claim 32, wherein the amount of lysostaphin analogue(s) administered is no more than 45 mg/kg/day.

55. (Amended) The method of [claim 34] Claim 58, wherein the amount of lysostaphin analogue(s) administered is no more than 45 mg/kg/day.

FULL TEXT OF CASES (USPQ FIRST SERIES)

Graham et al. v. John Deere Company of Kansas City et al.; Calmar, Inc. v. Cook Chemical Company; Colgate-Palmolive Company v. Same, 148 USPQ 459 (US SupCt 1966)

Graham et al. v. John Deere Company of Kansas City et al.; Calmar, Inc. v. Cook Chemical Company; Colgate-Palmolive Company v. Same, 148 USPQ 459 (US SupCt 1966)

**Graham et al. v. John Deere Company of Kansas City et al.;
Calmar, Inc. v. Cook Chemical Company; Colgate-Palmolive
Company v. Same**

**(US SupCt)
148 USPQ 459**

Decided Feb. 21, 1966

Nos. 11, 37, 43

U.S. Supreme Court

Headnotes

PATENTS

1. Patentability-Invention-In general (§ 51.501)

1952 Patent Act was intended to codify judicial precedents embracing principle announced in Hotchkiss v. Greenwood, 11 How. 248; while clear language of section 103 places emphasis on inquiry into obviousness, general level of innovation necessary to sustain patentability remains the same.

2. Patent grant-In general (§ 50.01)

Federal patent power stems from Article I, Section 8 of Constitution, which is both a grant of power and a limitation; this qualified authority is limited to promotion of advances in useful arts; in exercise of patent power, Congress may not overreach restraints imposed by constitutional purpose, nor may it enlarge patent monopoly without regard to the innovation, advancement, or social benefit gained thereby; Congress may not authorize issuance of patents whose effects are to remove existent knowledge from public domain or to restrict free access to materials already available; innovation, advancement, and things which add to sum of useful knowledge are inherent requisites in patent system which must promote progress of useful arts; this is standard expressed in Constitution and it may not be ignored; within limits of constitutional grant, Congress may select policy which in its judgment best effectuates the constitutional aim; within scope established by Constitution, Congress may set out conditions and tests for patentability; it is duty of Commissioner of Patents and courts in administration of patent system to give effect to constitutional standard by appropriate application of statutory scheme of Congress.

3. Patent grant-In general (§ 50.01)

Underlying policy of patent system is that benefit to public from the thing patented must outweigh restrictive effect of limited patent monopoly.

4. Patentability-Anticipation-In general (§ 51.201)

Patentability-Invention-In general (§ 51.501)

Patentability-Utility (§ 51.75)

Under 1952 Patent Act, patentability is dependent upon novelty, utility, and nonobviousness.

5. Patentability-Invention-In general (§ 51.501)

Patentability - Tests of - Flash of genius (§ 51.705)

Section 103 of 1952 Patent Act is a statutory expression of an additional requirement (nonobviousness) for patentability, originally expressed in *Hotchkiss v. Greenwood*, 11 How. 248; by last sentence, Congress intended to abolish test it believed Supreme Court announced in "flash of genius" phrase in *Cuno v. Automatic*, 314 U.S. 84, 51 USPQ 272; actually, "flash of genius" was mere rhetorical restatement that requirement that subject matter sought to be patented must be beyond skill of the calling; it was the device, not the invention, that had to reveal "flash of creative genius."

6. Patentability-Invention-In general (§ 51.501)

35 U.S.C. 103 was not intended by Congress to change general level of patentable invention, but was intended merely as a codification of judicial precedents embracing the *Hotchkiss* (11 How. 248) condition, with congressional directions that inquiries into obviousness of subject matter sought to be patented are a prerequisite to patentability.

7. Patentability-Invention-In general (§ 51.501)

Additional condition (nonobviousness) in 35 U.S.C. 103, when followed realistically, permits a more practical test of patentability; emphasis on nonobviousness is one of inquiry, not quality, and, as such, comports with constitutional strictures.

8. Patentability-Evidence of-Commercial success-In general (§ 51.4551)

Patentability - Evidence of - Delay and failure of others to produce invention _

Patentability-Invention-In general (§ 51.501)

Patentability - Invention - Law or fact question (§ 51.507)

While ultimate question of patent validity is one of law, condition in 35 U.S.C. 103, which is but one of three conditions, each of which must be satisfied, lends itself to several basic factual inquiries; under section 103, scope and content of prior art are to be determined, differences between prior art

and claims are to be ascertained, and level of ordinary skill in the pertinent art resolved; against this background, obviousness of subject matter is determined; such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to circumstances surrounding origin of subject matter sought to be patented; as indicia of obviousness, these inquiries may have relevancy.

9. Abandonment-Disclosure without claiming (§ 10.7)

Feature disclosed in patent drawings and specification, but not claimed therein, became public property.

10. Patentability-Tests of-In general (§ 51.701)

Patentability must be determined by consideration of subject matter sought to be patented taken as a whole.

11. Construction of specification and claims-By Patent Office proceedings-In general (§ 22.151)

Construction of specification and claims-By prior art (§ 22.20)

Construction of specification and claims-Claim defines invention (§ 22.30)

Invention is construed not only in light of claims, but also with reference to file wrapper or prosecution history in Patent Office; claims as allowed must be read and interpreted with reference to rejected ones and to state of prior art; claims that have been narrowed in order to obtain issuance of patent by distinguishing prior art cannot be sustained to cover that which was previously by limitation eliminated from patent.

12. Patentability - Evidence of - Commercial success-In general (§ 51.4551)

Patentability-Evidence of-Delay and failure of others to produce invention (§ 51.459)

Legal inferences or subtests (long-felt need, commercial success) focus attention on economic and motivational rather than technical issues and are, therefore, more susceptible to judicial treatment than are technical facts often present in patent litigation; they may aid judiciary and may serve to guard against slipping into hindsight and to resist temptation to read into prior art the teachings of invention in issue; however, they do not tip scales of patentability where differences from prior art were rendered apparent by prior patent before unsuccessful attempts to solve problem; it is irrelevant that no one chose to avail himself of knowledge stored in Patent Office and make a patent search.

Particular patents-Plow Clamp

2,627,798, Graham, Clamp for Vibrating Shank Plows, claims 1 and 2 invalid.

2,870,943, Scoggin, Pump-Type Liquid Sprayer Having Hold-down Cap, claims 1 and 2

Case History and Disposition:

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Action 1: On writ of certiorari to Court of Appeals for the Eighth Circuit; 142 USPQ 243. Action by William T. Graham and

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Graham Plow, Inc., against John Deere Company of Kansas City and Deere & Company for patent infringement. On writ of certiorari to review judgment for defendants. Affirmed. See also 137 USPQ 864, 144 USPQ 780. Action 2,3: On writs of certiorari to Court of Appeals for the Eighth Circuit; 142 USPQ 412. Two actions against Cook Chemical Company for declaratory judgment of patent invalidity and noninfringement, one by Calmar, Inc., and one by Colgate-Palmolive Company, in which defendant counterclaims for patent infringement. On writs of certiorari to review judgments for defendant. Reversed.

See also 138 USPQ 432, 144 USPQ 780.

Attorneys:

Action 1: Orville O. Gold (Claude A. Fishburn on the brief) both of Kansas City, Mo., for petitioners.

S. Thomas Morris, Amarillo, Tex. (W. W. Gibson, Amarillo, Tex., and Thomas E. Scofield, Kansas City, Mo., on the brief) for respondents.

Stanton T. Lawrence, Jr., Robert E. Isner, and Charles E. McKenney, all of New York, N.Y., filed brief for New York Patent Law Association, amicus curiae.

J. Vincent Martin, Alfred H. Evans, and Russell E. Schlorff, all of Houston, Tex., filed brief for Patent, Trademark and Copyright Section of the State Bar of Texas, amicus curiae.

Roger Robb, Washington, D.C., filed brief for American Bar Association, amicus curiae.

E. Ernest Goldstein and W. Page Keeton, both of Austin, Tex., filed brief amicus curiae.

George E. Frost and James M. Wetzel, both of Chicago, Ill., filed brief for Illinois State Bar Association, amicus curiae.

Action 2,3: Dennis G. Lyons, Washington, D.C. (Victor H. Kramer, Francis G. Cole, Watson, Cole, Grindle & Watson, and Arnold, Fortas & Porter, all of Washington, D.C., George H. Mortimer, New York, N.Y., and Howard A. Crawford, Jack W.R. Headley, and Lathrop, Righter, Gordon & Parker, all of Kansas City, Mo., on the brief) for petitioners.

Gordon D. Schmidt, Kansas City, Mo. (Hovey, Schmidt, Johnson & Hovey, Carl E. Enggas, and Watson, Ess, Marshall & Enggas, all of Kansas City, Mo., and Hugh B. Cox and Charles A. Miller, both of Washington, D.C., on the brief) for respondent.

Opinion By:

Mr. Justice Clark delivered the opinion of the Court.

Text

After a lapse of 15 years, the Court again focuses its attention on the patentability of inventions under the standard of Art. I, § 8, cl. 8. of the Constitution and under the conditions prescribed by the laws of the United States. Since our last expression on patent validity, *A. & P. Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 87 USPQ 303 (1950), the Congress has for the first time expressly added a third statutory dimension to the two requirements of novelty and utility that had been the sole statutory test since the Patent Act of 1793. This is the test of obviousness, i.e., "whether the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made." Patent Act of 1952, 66 Stat. 798, 35 U.S.C. § 103 (1964 ed.).

[1] The questions, involved in each of the companion cases before us, are what effect did the 1952 Act have upon traditional statutory and judicial tests of patentability and what definitive tests are now required. We have concluded that the 1952 Act was intended to codify judicial precedents embracing the principle long ago announced by this Court in *Hotchkiss v. Greenwood*, 11 How. 248 (1850), and that, while the clear language of § 103 places emphasis on an inquiry into obviousness, the general level of innovation necessary to sustain patentability remains the same.

I.

The Cases (a). No. 11, *Graham v. John Deere Co.*, an infringement suit by petitioners, presents a conflict between two Circuits over the validity of a single patent on a "Clamp for vibrating Shank Plows." The invention, a combination of old mechanical elements, involves a device designed to absorb shock from plow shanks as they plow through rocky soil and thus to prevent damage to the plow. In 1955, the Fifth Circuit had held the patent valid under its rule that when a combination produces an "old result in a cheaper and otherwise more advantageous way," it is patentable. *Jeoffroy Mfg., Inc. v. Graham*, 219 F.2d 511, 104 USPQ 261, cert. denied, 350 U.S. 826, 107 USPQ 362. In 1964, the Eighth Circuit held, in the case at bar, that there was no new result in the patented combination and that the patent was,

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therefore, not valid. 333 F.2d 529, 142 USPQ 243, reversing 216 F.Supp. 272, 137 USPQ 864. We granted certiorari, 379 U.S. 956, 144 USPQ 780. Although we have determined that neither Circuit applied the correct test, we conclude that the patent is invalid under § 103 and, therefore, we affirm the judgment of the Eighth Circuit. (b). No. 37, *Calmar, Inc. v. Cook Chemical Co.*, and No. 43, *Colgate-Palmolive Co. v. Cook Chemical Co.*, both from the Eighth Circuit, were separate declaratory judgment actions, but were filed contemporaneously. Petitioner in *Calmar* is the manufacturer of a finger-operated sprayer with a "hold-down" cap of the type commonly seen on grocer's shelves inserted in bottles of insecticides and other liquids prior to shipment. Petitioner in *Colgate-Palmolive* is a purchaser of the sprayers and uses them in the distribution of its products. Each action sought a declaration of invalidity and noninfringement of a patent on similar sprayers issued to Cook Chemical as assignee of Baxter I. Scoggin, Jr., the inventor. By cross-action, Cook Chemical claimed infringement. The actions were consolidated for trial and the patent was sustained by the District Court. 220 F.Supp. 414, 138 USPQ 432. The Court of Appeals affirmed, 336 F.2d 110, 142 USPQ 412, and we granted certiorari, 380 U.S. 949. We reverse. Manifestly, the validity of each of these patents turns on the facts. The basic problems, however, are the same in each case and require initially a discussion of the constitutional and statutory provisions covering the patentability of the inventions.

II.

[2] At the outset it must be remembered that the federal patent power stems from a specific constitutional provision which authorizes the Congress "To promote the Progress of * * * useful Arts, by securing for limited Times to * * * Inventors the exclusive Right to their * * * Discoveries * * *." Art. I, § 8. ¹The clause is both a grant of power and a limitation. This qualified authority, unlike the power often exercised in the Sixteenth and Seventeenth Centuries by the English Crown, is limited to the promotion of advances in the "useful arts." It was written against the backdrop of the practices-eventually curtailed by the Statute of Monopolies-of the Crown in granting monopolies to court favorites in goods or businesses which had long before been enjoyed by the public. See Meinhardt, *Inventions, Patents and Monopoly*, pp. 30-35 (London, 1946). The Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby. Moreover, Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available. Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must "promote the Progress of * * * useful Arts." This is the *standard* expressed in the Constitution and it may not be ignored. And it is in this light that patent "validity requires reference to a standard written into the Constitution." *A. & P. Tea Co. v. Supermarket Corp.*, *supra*, at 154, 87 USPQ at 306. Within the limits of the constitutional grant, the Congress may, of course, implement the stated purpose of the Framers by selecting the policy which in its judgment best effectuates the constitutional aim. This is but a corollary to the grant to Congress of any Article I power. *Gibbons v. Ogden*, 9 Wheat. 1. Within the scope established by the Constitution, Congress may set out conditions and tests for patentability. *McClurg v. Kingsland*, 1 How. 202, 206. It is the duty of the Commissioner of Patents and of the courts in the administration of the patent system to give effect to the constitutional standard by appropriate application, in each case, of the statutory scheme of the Congress. Congress quickly responded to the bidding of the Constitution by enacting the Patent Act of 1790 during the second session of the First Congress. It created an agency in the Department of State headed by the Secretary of State, the Secretary of the Department of War and the Attorney General, any two of whom could issue a patent for a period not exceeding 14 years to any petitioner that "hath invented or discovered any useful art, manufacture, or device, or any improvement therein not before known or used" if the Board found that "the invention or discovery [was] sufficiently useful and important * * *." This group, whose members administered the patent system along with their

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other public duties, was known by its own designation as "Commissioners for the Production of the Useful Arts." Thomas Jefferson, who as Secretary of State was a member of the group, was its moving spirit and might well be called the "First Administrator of our Patent System." See Federico, *Operation of the Patent Act of 1790*, 18 J. P. O. S. 237, 238 (1936). He was not only an administrator of the patent system under the 1790 Act, but was also the author of the 1793 Patent Act. In addition, Jefferson was himself an inventor of great note. His unpatented improvements on plows, to mention but one of his inventions, won acclaim and recognition on both sides of the Atlantic. Because of his active interest and influence in the early development of the patent system, Jefferson's views on the general nature of the limited patent monopoly under the Constitution, as well as his conclusions as to conditions for patentability under the statutory scheme, are worthy of note. Jefferson, like other Americans, had an instinctive aversion to monopolies. It was a monopoly on tea that sparked the Revolution and Jefferson certainly did not favor an equivalent form of monopoly under the new government. His abhorrence of monopoly extended initially to patents as well. From France, he wrote to Madison urging a bill of rights provision restricting monopoly, and as against the argument that limited monopoly might serve to incite "ingenuity," he argued forcefully that "the benefit of even limited monopolies is too doubtful to be opposed to that of their general suppression," IV Writings of Thomas Jefferson (Ford ed.), at 476 (July 1788). His views ripened, however, and in another letter to Madison after the adoption of the Bill of Rights, Jefferson stated that he would have been pleased by an express provision in this form:

"Article 9. Monopolies may be allowed to persons for their own productions in literature, and their own inventions in the Arts, for a term not exceeding-years, but for no longer term and for no other purpose." *Id.*, at 493 (Aug. 1789).

And he later wrote:

"Certainly an inventor ought to be allowed a right to the benefit of his invention for some certain time * * *. Nobody wishes more than I do that ingenuity should receive liberal encouragement." Letter to Oliver Evans, V Writings of Thomas Jefferson, (Washington ed.), at 75 (1807). Jefferson's philosophy on the nature and purpose of the patent monopoly is expressed in a letter to Isaac McPherson, a portion of which we set out in the margin.² He rejected a natural rights theory in intellectual property rights and clearly recognized the social and economic rationale of the patent system. The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge. The grant of an exclusive right to an invention was the creation of society-at odds with the inherent free nature of disclosed ideas-and was not to be freely given. Only inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly. Jefferson did not believe in granting patents for small details, obvious improvements, or frivolous devices. His writings evidence his insistence upon a high level of patentability. As a member of the patent board for several years, Jefferson saw clearly the

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difficulty in "drawing a line between things which are worth to the public the embarrassment of an exclusive patent and those which are not." The board on which he served sought to draw such a line and formulated several rules which are preserved in Jefferson's correspondence.³ Despite the Board's efforts, Jefferson saw "with what slow progress a system of general rules could be matured." Because of the "abundance" of cases and the fact that the investigations occupied "more time of the members of the board than they could spare from their higher duties, the whole was turned over to the judiciary, to be matured into a system, under which everyone might know when his actions were safe and lawful." Letter to McPherson, *supra*, at 181. Apparently Congress agreed with Jefferson and the Board that the courts should develop additional, conditions for patentability. Although the Patent Act was amended, revised or codified some 50 times between 1790 and 1950, Congress steered clear of a statutory set of requirements other than the bare novelty and utility tests reformulated in Jefferson's draft of the 1793 Patent Act.

III.

[3] The difficulty of formulating conditions for patentability was heightened by the generality of the constitutional grant and the statutes implementing it, together with the underlying policy of the patent system that "the things which are worth to the public the embarrassment of an exclusive patent," as Jefferson put it, must outweigh the restrictive effect of the limited patent monopoly. The inherent problem was to develop some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent. This Court formulated a general condition of patentability in 1850 in *Hotchkiss v. Greenwood*, 11 How. 248. The patent involved a mere substitution of materials-porcelain or clay for wood or metal in door knobs-and the Court condemned it, holding:⁴

"[U]nless more ingenuity and skill * * * were required than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention. In other words, the improvement is the work of a skilled mechanic, not that of the inventor." At p. 267. *Hotchkiss*, by positing the condition that a patentable invention evidence more ingenuity and skill than that possessed by an ordinary mechanic acquainted with the business, merely distinguished between new and useful innovations that were capable of sustaining a patent and those that were not. The *Hotchkiss* test laid the cornerstone of the

judicial evolution suggested by Jefferson and left to the courts by Congress. The language in the case, and in those which followed, gave birth to "invention" as a word of legal art signifying patentable inventions. Yet, as this Court has observed, "[t]he truth is the word ['invention'] cannot be defined in such a manner as to afford any substantial aid in determining whether a particular device involves an exercise of inventive faculty or not." *McClain v. Ortmyer*, 141 U.S. 419, 427 (1891), *A. & P. Tea Co. v. Supermarket Corp.*, 340 U.S. at 151, 87 USPQ at 305. Its use as a label brought about a large variety of opinions as to its meaning both in the Patent Office, in the courts, and at the bar. The Hotchkiss formulation, however, lies not in any label, but in its functional approach to questions of patentability. In practice, Hotchkiss has required a comparison between the subject matter of the patent, or patent application, and the background skill of the calling. It has been from this comparison that patentability was in each case determined.

IV.

The 1952 Act .

[4] The Act sets out the conditions of patentability in three sections. An analysis of the structure of these three sections indicates that patentability is

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dependent upon three explicit conditions: novelty and utility as articulated and defined in § 101, and § 102, and nonobviousness, the new statutory formulation, as set out in § 103. The first two sections, which trace closely the 1874 codification, express the "new and useful" tests which have always existed in the statutory scheme and, for our purposes here, need no clarification. ²The pivotal section around which the present controversy centers is § 103. It provides:

"§ 103. Conditions for patentability; non-obvious subject matter

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made." The section is cast in relatively unambiguous terms. Patentability is to depend, in addition to novelty and utility, upon the "non-obvious" nature of the "subject matter sought to be patented" to a person having ordinary skill in the pertinent art. The first sentence of this section is strongly reminiscent of the language in Hotchkiss. Both formulations place emphasis on the pertinent art existing at the time the invention was made and both are implicitly tied to advances in that art. The major distinction is that Congress has emphasized "non-obviousness" as the operative test of the section, rather than the less definite "invention" language of Hotchkiss that Congress thought had lead to "a large variety" of expressions in decisions and writings. In the title itself the Congress used the phrase "Conditions for patentability: *non-obvious subject matter* , " thus focusing upon "non-obviousness" rather than "invention." ³The Senate and House Reports, S. Rep. No. 1979, 82d Cong., 2d Sess. (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess. (1952), reflect this emphasis in these terms:

"Section 103, for the first time in our statute, provides a condition which exists in the law and has existed for more than 100 years, but only by reason of decision of the Courts. An invention which has been made, and which is new in the sense that the same thing has not been made before, may still not be patentable if the difference between the new thing and what was known before is not considered sufficiently great to warrant a patent. That has been expressed in a large variety of ways in decisions of the courts and in writings. Section 103 states this requirement in the title. It refers to the difference between the subject matter sought to be patented and the prior art, meaning

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what was known before as described in section 102. If this difference is such that the subject matter as a whole would have been obvious at the time to a person skilled in the art, then the subject matter cannot be patented.

"That provision paraphrases language which has often been used in decisions of the courts, and the section is added to the statute for uniformity and definiteness. This section should have a stabilizing effect and minimize great departures which have appeared in some cases." H.R. Rep., at 7; S. Rep., at 6.

[5] It is undisputed that this section was, for the first time, a statutory expression of an additional requirement for patentability, originally expressed in *Hotchkiss*. It also seems apparent that Congress intended by the last sentence of § 103 to abolish the test it believed this Court announced in the controversial phrase "flash of genius," used in *Cuno Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 51 USPQ 272 (1941).² It is contended, however, by some of the parties and by several of the amici that the first sentence of § 103 was intended to sweep away judicial precedents and to lower the level of patentability. Others contend that the Congress intended to codify the essential purpose reflected in existing judicial precedents—the rejection of insignificant variations and innovations of a commonplace sort—and also to focus inquiries under § 103 upon nonobviousness, rather than upon "invention," as a means of achieving more stability and predictability in determining patentability and validity. The Reviser's Note to this section,³ with apparent reference to *Hotchkiss*, recognizes that judicial requirements as to "lack of patentable novelty have been followed since at least as early as 1850." The note indicates that the section was inserted because it "may have some stabilizing effect and also serve as a basis for the addition at a later time of criteria which may be worked out." To this same effect are the reports of both Houses, *supra*, which state that the first sentence of the section "paraphrases the language which has often been used in decisions of the courts and the section is added to the statute for uniformity and definitiveness."

[6] We believe that this legislative history, as well as other sources,² show that the revision was not intended by Congress to change the general level of patentable invention. We conclude that the section was intended merely as a codification of judicial precedents embracing the *Hotchkiss* condition, with congressional directions that inquiries into the obviousness of the subject matter sought to be patented are a prerequisite to patentability.

V.

[7] Approached in this light, the § 103 additional condition, when fol

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lowed realistically, will permit a more practical test of patentability. The emphasis on nonobviousness is one of inquiry, not quality and, as such, comports with the constitutional strictures.

[8] While the ultimate question of patent validity is one of law, *A. & P. Tea Co. v. Supermarket Corp.*, *supra*, at 155, 87 USPQ at 307, the § 103 condition, which is but one of three conditions, each of which must be satisfied, lends itself to several basic factual inquiries. Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy. See Note, Subtests of "Nonobviousness," 112 U. Pa. L. Rev. 1169 (1964). This is not to say, however, that there will not be difficulties in applying the nonobviousness test. What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context. The

difficulties, however, are comparable to those encountered daily by the courts in such frames of reference as negligence and scienter, and should be amenable to a case-by-case development. We believe that strict observance of the requirements laid down here will result in that uniformity and definitiveness which Congress called for in the 1952 Act. While we have focused attention on the appropriate standard to be applied by the courts, it must be remembered that the primary responsibility for sifting out unpatentable material lies in the Patent Office. To await litigation is-for all practical purposes-to debilitate the patent system. We have observed a notorious difference between the standards applied by the Patent Office and by the courts. While many reasons can be adduced to explain the discrepancy, one may well be the free rein often exercised by examiners in their use of the concept of "invention." In this connection we note that the Patent Office is confronted with a most difficult task. Almost 100,000 applications for patents are filed each year. Of these, about 50,000 are granted with the result that the backlog now runs well over 200,000. United States Patent Office, Index of Patents, p. 1123 (1963). This is itself a compelling reason for the Commissioner to strictly adhere to the 1952 Act as interpreted here. This would we believe, not only expedite disposition but bring about a closer concurrence between administrative and judicial precedent. ¹⁰ Although we conclude here that the inquiry which the Patent Office and the courts must make as to patentability must be beamed with greater intensity on the requirements of § 103, it bears repeating that we find no change in the general strictness with which the overall test is to be applied. We have been urged to find in § 103 a relaxed standard, supposedly a congressional reaction to the "increased standard" applied by this Court in its decisions over the last 20 or 30 years. The standard has remained invariable in this Court. Technology, however, has advanced-and with remarkable rapidity in the last 50 years. Moreover the ambit of applicable art in given fields of science has widened by disciplines unheard of a half-century ago. It is but an evenhanded application to require those persons granted the benefit of a patent monopoly be charged with an awareness of these changed conditions. The same is true of the less technical, but still useful arts. He who seeks to build a better mousetrap today has a long path to tread before reaching the Patent Office.

VI. We now turn to the application of the conditions found necessary for patentability to the cases involved here:

A. The patent in issue in No. 11, *Graham v. John Deere Co.* This patent, No. 2,627,798 (hereinafter called the '798 patent) relates to a spring clamp which permits plow shanks to be pushed upward when they hit obstructions in the soil, and then springs the shanks back into normal position when the obstruction is passed over. The device, which we show diagrammatically in the accompanying sketches (Appendix, Fig. 1), is fixed to the plow frame as a unit. The mechanism around which the controversy centers is basically a hinge. The top

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half of it, known as the upper plate (marked 1 in the sketches), is a heavy metal piece clamped to the plow frame (2) and is stationary relative to the plow frame. The lower half of the hinge, known as the hinge plate (3), is connected to the rear of the upper plate by a hinge pin (4) and rotates downward with respect to it. The shank (5), which is bolted to the forward end of the hinge plate (at 6), runs beneath the plate and parallel to it for about nine inches, passes through a stirrup (7), and then continues backward for several feet curving down toward the ground. The chisel (8), which does the actual plowing, is attached to the rear end of the shank. As the plow frame is pulled forward, the chisel rips through the soil, thereby plowing it. In the normal position, the hinge plate and the shank are kept tight against the upper plate by a spring (9), which is atop the upper plate. A rod (10) runs through the center of the spring, extending down through holes in both plates and the shank. Its upper end is bolted to the top of the spring while its lower end is hooked against the underside of the shank. When the chisel hits a rock or other obstruction in the soil, the obstruction forces the chisel and the rear portion of the shank to move upward. The shank is pivoted (at 11) against the rear of the hinge plate and pries open the hinge against the closing tendency of the spring. (See sketch labeled "Open Position," Appendix, Fig. 1.). This closing tendency is caused by the fact that, as the hinge is opened, the connecting rod is pulled downward and the spring is

compressed. When the obstruction is passed over, the upward force on the chisel disappears and the spring pulls the shank and hinge plate back into their original position. The lower, rear portion of the hinge plate is constructed in the form of a stirrup (6) which brackets the shank, passing around and beneath it. The shank fits loosely into the stirrup (permitting a slight up and down play). The stirrup is designed to prevent the shank from recoiling away from the hinge plate, and thus prevents excessive strain on the shank near its bolted connection. The stirrup also girds the shank, preventing it from fishtailing from side to side. In practical use, a number of spring-hinge-shank combinations are clamped to a plow frame, forming a set of ground-working chisels capable of withstanding the shock of rocks and other obstructions in the soil without breaking the shanks.

Background of the Patent . Chisel plows, as they are called, were developed for plowing in areas where the ground is relatively free from rocks or stones. Originally, the shanks were rigidly attached to the plow frames. When such plows were used in the rocky glacial soils of some of the Northern States, they were found to have serious defects. As the chisels hit buried rocks, a vibratory motion was set up and tremendous forces were transmitted to the shank near its connection to the frame. The shanks would break. Graham, one of the petitioners, sought to meet that problem, and in 1950 obtained a patent, U.S. No. 2,493,811, on a spring clamp which solved some of the difficulties. Graham and his companies manufactured and sold the '811 clamps. In 1950, Graham modified the '811 structure and filed for a patent. That patent, the one in issue, was granted in 1953. This suit against competing plow manufacturers resulted from charges by petitioners that several of respondents' devices infringed the '798 patent.

The Prior Art . Five prior patents indicating the state of the art were cited by the Patent Office in the prosecution of the '798 application. Four of these patents, 10 other United States patents and two prior use spring clamp arrangements not of record in the '798 file wrapper were relied upon by respondent as revealing the prior art. The District Court and the Court of Appeals found that the prior art "as a whole in one form or another contains all of the mechanical elements of the '798 Patent." One of the prior use clamp devices not before the Patent Examiner-Glencoe-was found to have "all of the elements." We confine our discussion to the prior patent of Graham, '811, and to the Glencoe clamp device, both among the references asserted by respondents. The Graham '811 and '798 patent devices are similar in all elements, save two; (1) the stirrup and the bolted connection of the shank to the hinge plate do not appear in '811; and (2) the position of the shank is reversed, being placed in patent '811 above the hinge plate, sandwiched between it and the upper plate. The shank is held in place by the spring rod which is hooked against the bottom of the hinge plate passing through a slot in the shank. Other differences are of no consequence to our examination. In practice the '811 patent arrangement permitted the shank to wobble or fishtail because it was not rigidly fixed to the hinge plate; moreover, as the hinge plate was below the

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shank, the latter caused wear on the upper plate, a member difficult to repair or replace. Graham's '798 patent application contained 12 claims. All were rejected as not distinguished from the Graham '811 patent. The inverted relationship of the shank was specifically rejected as was the bolting of the shank to the hinge plate. The Patent Office examiner found these to be "matters of design well within the expected skill of the art and devoid of invention." Graham withdrew the original claims and substituted the two new ones which are substantially those in issue here. His contention was that wear was reduced in patent '798 between the shank and the heel or rear of the upper plate. ¹¹He also emphasized several new features, the relevant one here being that the bolt used to connect the hinge plate and shank maintained the upper face of the shank in continuing and constant contact with the underface of the hinge plate. Graham did not urge before the Patent Office the greater "flexing" qualities of the '798 patent arrangement which he so heavily relied on in the courts. The sole element in patent '798 which petitioners argue before us is the interchanging of the shank and hinge plate and the consequences flowing from this arrangement. The contention is that this arrangement - which petitioners claim is not disclosed in the prior art-permits the shank to flex under stress for its *entire* length. As we have sketched (see sketch, "Graham '798 Patent" in Appendix, Fig. 2), when

the chisel hits an obstruction the resultant force (A) pushes the rear of the shank upward and the shank pivots at the underface of the upper plate at its rear (C). The natural tendency is for that portion of the shank between the pivot point and the bolted connection (i.e., between C and D) to bow downward and away from the hinge plate. The maximum distance (B) that the shank moves away from the plate is slight - for emphasis, greatly exaggerated in the sketches. This is so because of the strength of shank and the short-nine inches or so-length of that portion of the shank between (C) and (D). On the contrary, in patent '811 (see sketch, "Graham '811 Patent" in Appendix, Fig. 2), the pivot points is the upper plate at point (c); and while the tendency for the shank to bow between points (c) and (d) is the same as in '798, the shank is restricted because of the underlying hinge and cannot flex as freely. In practical effect, the shank flexes only between points (a) and (c), and not along the entire length of the shank, as in '798. Petitioners say that this difference in flex, though small, effectively absorbs the tremendous forces of the shock of obstructions whereas prior art arrangements failed.

The Obviousness of the Differences . We cannot agree with petitioners. We assume that the prior art does not disclose such an arrangement as petitioners claim in patent '798. Still we do not believe that the argument on which petitioners' contention is bottomed supports the validity of the patent. The tendency of the shank to flex is the same in all cases. If free-flexing, as petitioners now argue, is the crucial difference above the prior art, then it appears evident that the desired result would be obtainable by not boxing the shank within the confines of the hinge. ¹²The only other effective place available in the arrangement was to attach it below the hinge plate and run it through a stirrup or bracket that would not disturb its flexing qualities. Certainly a person having ordinary skill in the prior art, given the fact that the flex in the shank could be utilized more effectively if allowed to run the entire length of the shank, would immediately see that the thing to do was what Graham did, i.e., invert the shank and the hinge plate. Petitioners' argument basing validity on the free-flex theory raised for the first time on appeal is reminiscent of *Lincoln Engineering Co. v. Stewart-Warner Corp.*, 303 U.S. 545, 37 USPQ 1, 3 (1938), where the Court called such

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an effort "an afterthought. No such function * * * is hinted at in the specifications of the patent. If this were so vital an element in the functioning of the apparatus it is strange that all mention of it was omitted." At p. 550, 37 USPQ at 3. No "flexing" argument was raised in the Patent Office. Indeed, the trial judge specifically found that "flexing is not a claim of the patent in suit * * *" and would not permit interrogation as to flexing in the accused devices. Moreover, the clear testimony of petitioners' experts shows that the flexible advantages flowing from the '798 arrangement are not, in fact, a significant feature in the patent. ¹³We find no nonobvious facets in the '798 arrangement. The wear and repair claims were sufficient to overcome the patent examiner's original conclusions as to the validity of the patent. However, some of the prior art, notably *Glencoe*, was not before him. There the hinge plate is below the shank but, as the courts below found, all of the elements in the '798 patent are present in the *Glencoe* structure. Furthermore, even though the position of the shank and hinge plate appears reversed in *Glencoe*, the mechanical operation is identical. The shank there pivots about the underside of the stirrup, which in *Glencoe* is *above* the shank. In other words, the stirrup in *Glencoe* serves exactly the same function as the heel of the hinge plate in '798. The mere shifting of the wear point to the heel of the '798 hinge plate from the stirrup of *Glencoe*-itself a part of the hinge plate-presents no operative mechanical distinctions, much less nonobvious differences.

B. The Patent in issue in No. 37, Calmar, Inc. v. Cook Chemical Co. and in No. 43, Colgate Palmolive Co. v. Cook Chemical Co. . The single patent ¹⁴involved in these cases relates to a plastic finger sprayer with a "hold down" lid used as a built-in dispenser for containers or bottles packaging liquid products, principally household insecticides. Only the first two of the four claims in the patent are involved here and we, therefore, limit our discussion to them. We do not set out those claims here since they are printed in 220 F.Supp., at pp. 417-418, 138 USPQ at 435. In essence the device here combines a finger-operated pump sprayer, mounted in a container or bottle by means of a container cap, with a plastic overcap which screws over the top of and depresses the sprayer (see

Figure 3 in the Appendix). The pump sprayer passes through the container cap and extends down into the liquid in the container; the overcap fits over the pump sprayer and screws down on the outside of the collar mounting or retainer which is molded around the body of the sprayer. When the overcap is screwed down on this collar mounting a seal is formed by the engagement of a circular ridge or rib located above the threads on the collar mounting with a mating shoulder located inside the overcap above its threads. ¹⁵The overcap, as it is screwed down, depresses the pump plunger rendering the pump inoperable and when the seal is effected, any liquid which might seep into the overcap through or around the pump is prevented from leaking out of the overcap. The overcap serves also to protect the sprayer head and prevent damage to it during shipment or merchandising. When the overcap is in place it does not reach the cap of the container or bottle and in no way engages it since a slight space is left between those two pieces. The device, called a shipper-sprayer in the industry, is sold as an integrated unit with the overcap in place enabling the insecticide manufacturer to install it on the container or bottle of liquid in a single operation in an automated bottling process. The ultimate consumer simply unscrews and discards the overcap, the pump plunger springs up and the sprayer is ready for use.

The Background of the Patent . For many years manufacturers engaged in the insecticide business had

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faced a serious problem in developing sprayers that could be integrated with the containers or bottles in which the insecticides were marketed. Originally, insecticides were applied through the use of tin sprayers, not supplied by the manufacturer. In 1947, Cook Chemical, an insecticide manufacturer, began to furnish its customers with plastic pump dispensers purchased from Calmar. The dispenser was an unpatented finger-operated device mounted in a perforated cardboard holder and hung over the neck of the bottle or container. It was necessary for the ultimate consumer to remove the cap of the container and insert and attach the sprayer to the latter for use. Hanging the sprayer on the side of the container or bottle was both expensive and troublesome. Packaging for shipment had to be a hand operation, and breakage and pilferage as well as the loss of the sprayer during shipment and retail display often occurred. Cook Chemical urged Calmar to develop an integrated sprayer that could be mounted directly in a container or bottle during the automated filling process and that would not leak during shipment or retail handling. Calmar did develop some such devices but for various reasons they were not completely successful. The situation was aggravated in 1954 by the entry of Colgate-Palmolive into the insecticide trade with its product marketed in aerosol spray cans. These containers, which used compressed gas as a propellant to dispense the liquid, did not require pump sprayers. During the same year Calmar was acquired by the Drackett Company. Cook Chemical became apprehensive of its source of supply for pump sprayers and decided to manufacture its own through a subsidiary, Bakan Plastics, Inc. Initially, it copied its design from the unpatented Calmar sprayer, but an officer of Cook Chemical, Scoggin, was assigned to develop a more efficient device. By 1956 Scoggin had perfected the shipper-sprayer in suit and a patent was granted in 1959 to Cook Chemical as his assignee. In the interim Cook Chemical began to use Scoggin's device and it was also marketed to the trade. The device was well received and soon became widely used. In the meanwhile, Calmar employed two engineers, Corsett and Coopridner, to perfect a shipper-sprayer and by 1958 it began to market its SS-40, a device very much similar to Scoggin's. When the Scoggin patent issued, Cook Chemical charged Calmar's SS-40 with infringement and this suit followed.

The Opinions of the District Court and the Court of Appeals. At the outset it is well to point up that the parties have always disagreed as to the scope and definition of the invention claimed in the patent in suit. Cook Chemical contends that the invention encompasses a unique combination of admittedly old elements and that patentability is found in the result produced. Its expert testified that the invention was "the first commercially successful, inexpensive, integrated shipping closure pump unit which permitted automated assembly with a container of household insecticide or similar liquids to produce a practical ready-to-use package which should be shipped without external leakage and

which was so organized that the pump unit with its hold-down cap could be itself assembled and sealed and then later assembled and sealed on the container without breaking the first seal." Cook Chemical stresses the long-felt need in the industry for such a device; the inability of others to produce it; and its commercial success—all of which, contends Cook, evidences the nonobvious nature of the device at the time it was developed. On the other hand, Calmar says that the differences between Scoggin's shipper-sprayer and the prior art relate only to the design of the overcap and that the differences are so inconsequential that the device as a whole would have been obvious at the time of its invention to a person having ordinary skill in the art. Both courts accepted Cook Chemical's contentions. While the exact basis of the District Court's holding is uncertain, it did find the subject matter of the patent new, useful and nonobvious. It concluded that Scoggin "had produced a sealed and protected sprayer unit which the manufacturer need only screw onto the top of its container much in the same fashion as a simple cap." 220 F.Supp. at 418, 138 USPQ at 436. Its decision seems to be bottomed on the finding that the Scoggin sprayer solved the long-standing problem that had confronted the industry. ¹⁶The Court of Appeals also found validity in the

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"novel 'marriage' of the sprayer with the insecticide container" which took years in discovery and in "the immediate commercial success" which it enjoyed. While finding that the individual elements of the invention were "not novel per se" the court found "nothing in the prior art suggesting Scoggin's unique combination of these old features as would solve the problem * * * which for years beset the insecticide industry." It concluded that "the * * * [device] * * * meets the exacting standard required for a combination of old elements to rise to the level of patentable invention by fulfilling the long-felt need with an economical, efficient, utilitarian apparatus which achieved novel results and immediate commercial success." 336 F.2d at 114, 142 USPQ at 415.

The Prior Art . Only two of the five prior art patents cited by the Patent Office Examiner in the prosecution of Scoggin's application are necessary to our discussion, i.e., Lohse U.S. Patent No. 2,119,884 (1938) and Mellon U.S. Patent No. 2,586,687 (1952). Others are cited by Calmar that were not before the examiner, but of these our purposes require discussion only of the Livingstone U.S. Patent No. 2,751,480 (1953). Simplified drawings of each of these patents are reproduced in the Appendix, Figs. 4-6 for comparison and description. The Lohse patent (Fig. 4) is a shipper-sprayer designed to perform the same function as Scoggin's device. The differences, recognized by the District Court, are found in the overcap seal which in Lohse is formed by the skirt of the overcap engaging a washer or gasket which rests upon the upper surface of the container cap. The court emphasized that in Lohse "there are no seals above the threads and below the sprayer head." 220 F.Supp. at 419-420. 138 USPQ at 437. The Mellon patent (Fig. 5), however, discloses the idea of effecting a seal above the threads of the overcap. Mellon's device, likewise a shipper-sprayer, differs from Scoggin's in that its overcap screws directly on the container, and a gasket, rather than a rib, is used to effect the seal. Finally, Livingstone (Fig. 6) shows a seal above the threads accomplished without the use of a gasket or washer. ¹⁷Although Livingstone's arrangement was designed to cover and protect pouring spouts, his sealing feature is strikingly similar to Scoggin's. Livingstone uses a tongue and groove technique in which the tongue, located on the upper surface of the collar, fits into a groove on the inside of the overcap. Scoggin employed the rib and shoulder seal in the identical position and with less efficiency because the Livingstone technique is inherently a more stable structure, forming an interlock that withstands distortion of the overcap when subjected to rough handling. Indeed, Cook Chemical has now incorporated the Livingstone closure into its own shipper-sprayers as had Calmar in its SS-40.

The Invalidity of the Patent .

[10] Let us first return to the fundamental disagreement between the parties. Cook Chemical, as we noted at the outset, urges that the invention must be viewed as the overall combination, or-putting it in the language of the statute—that we must consider the subject matter sought to be patented taken as a whole. With this position, taken in the abstract there is of course no quibble. But the history of the

prosecution of the Scoggin application in the Patent Office reveals a substantial divergence in respondent's present position. As originally submitted, the Scoggin application contained 15 claims which in very broad terms claimed the entire combination of spray pump and overcap. No mention of, or claim for, the sealing features were made. All 15 claims were rejected by the examiner because (1) the applicant was vague and indefinite as to what the invention was, and (2) the claims were met by Lohse. Scoggin canceled these claims and submitted new ones. Upon a further series of rejections and new submissions, the Patent Office Examiner, after an office interview, at last relented. It is crystal-clear that after the first rejection, Scoggin relied entirely upon the sealing arrangement as the exclusive patentable difference in his combination. It is likewise clear that it was on that feature that the examiner allowed the claims. In fact, in a letter accompanying the final submission of claims, Scoggin, through his attorney, stated that "agreement was reached between the Honorable Examiner and applicant's attorney relative to *limitations* which must be in the claims in order to define novelty over the previously applied disclosure of

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Lohse when considered in view of the newly cited patents of Mellon and Darley, Jr." (Italics added.) Moreover, those limitations were specifically spelled out as (1) the use of a rib seal and (2) an overcap whose lower edge did not contact the container cap. Mellon was distinguished, as was the Darley patent, *infra*, n. 18, on the basis that although it disclosed a hold-down cap with a seal located above the threads, it did not disclose a rib seal disposed in such position as to cause the lower peripheral edge of the overcap "to be maintained out of contacting relationship with [the container] cap * * * when * * * [the overcap] was screwed [on] tightly * * *." Scoggin maintained that the "obvious modification" of Lohse in view of Mellon would be merely to place the Lohse gasket above the threads with the lower edge of the overcap remaining in tight contact with the container cap or neck of the container itself. In other words, the Scoggin invention was limited to the use of a rib-rather than a washer or gasket-and the existence of a slight space between the overcap and the container cap.

[11] It is, of course, well-settled that an invention is construed not only in the light of the claims, but also with reference to the file wrapper or prosecution history in the Patent Office. *Hogg v. Emerson*, 11 How. 587 (1850); *Crawford v. Heysinger*, 123 U.S. 589 (1887). Claims as allowed must be read and interpreted with reference to rejected ones and to the state of the prior art; and claims that have been narrowed in order to obtain the issuance of a patent by distinguishing the prior art cannot be sustained to cover that which was previously by limitation eliminated from the patent. *Powers-Kennedy Co. v. Concrete Co.*, 282 U.S. 175, 185-186, 7 USPQ 122, 126 (1930); *Schriber Co. v. Cleveland Trust Co.*, 311 U.S. 211, 220-221, 47 USPQ 345, 348-349 (1940). Here, the patentee obtained his patent only by accepting the limitations imposed by the examiner. The claims were carefully drafted to reflect these limitations and Cook Chemical is not now free to assert a broader view of Scoggin's invention. The subject matter as a whole reduces, then, to the distinguishing features clearly incorporated into the claims. We now turn to those features. As to the space between the skirt of the overcap and the container cap, the District Court found:

FULL TEXT OF CASES (USPQ2D)

All Other Cases

In re Vaeck (CA FC) 20 USPQ2d 1438 (10/21/1991)

In re Vaeck (CA FC) 20 USPQ2d 1438

In re Vaeck**U.S. Court of Appeals Federal Circuit**
20 USPQ2d 1438**Decided October 21, 1991**
No. 91-1120**Headnotes****PATENTS****1. Patentability/Validity - Obviousness - Combining references (§ 115.0905)**

Rejection of claimed subject matter as obvious under 35 USC 103 in view of combination of prior art references requires consideration of whether prior art would have suggested to those of ordinary skill in art that they should make claimed composition or device, or carry out claimed process, and whether prior art would also have revealed that such person would have reasonable expectation of success; both suggestion and reasonable expectation of success must be founded in prior art, not in applicant's disclosure.

2. Patentability/Validity - Obviousness - Relevant prior art - Particular inventions
(§ 115.0903.03)

Patent and Trademark Office has failed to establish prima facie obviousness of claims for use of genetic engineering techniques for producing proteins that are toxic to insects such as larvae of mosquitos and black flies, since prior art does not disclose or suggest expression in cyanobacteria of chimeric gene encoding insecticidally active protein, or convey to those of ordinary skill reasonable expectation of success in doing so; expression of antibiotic resistance-conferring genes in cyanobacteria, without more, does not render obvious expression of unrelated genes in cyanobacteria for unrelated purposes.

3. Patentability/Validity - Specification - Enablement (§ 115.1105)

JUDICIAL PRACTICE AND PROCEDURE

Procedure - Judicial review - Standard of review - Patents (§ 410.4607.09)

Specification must, in order to be enabling as required by 35 USC 112, first paragraph, teach person skilled in art to make and use invention without "undue experimentation," which does not preclude some experimentation; enablement is question of law which is reviewed independently on appeal, although such determination is based upon underlying factual findings which are reviewed for clear error.

PATENTS

4. Patentability/Validity - Specification - Enablement (§ 115.1105)

Patent and Trademark Office did not err in rejecting, as non-enabling pursuant to 35 USC 112, first paragraph, claims for use of genetic engineering techniques for producing proteins that are toxic to insects such as larvae of mosquitos and black flies, in view of relatively incomplete understanding of biology of cyanobacteria as of applicants' filing date, as well as limited disclosure by applicants of particular cyanobacterial genera operative in claimed invention, since there is no reasonable correlation between narrow disclosure in applicants' specification and broad scope of protection sought in claims encompassing gene expression in any and all cyanobacteria.

Case History and Disposition:

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Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application for patent, serial no. 07/021,405, filed March 4, 1987, by Mark A. Vaeck, Wipa Chungjatupornchai, and Lee McIntosh (hybrid genes incorporating a DNA fragment containing a gene coding for an insecticidal protein, plasmids, transformed cyanobacteria expressing such protein and method for use as a biocontrol agent). From decision rejecting claims 1-48 and 50-52 as unpatentable under 35 USC 103, and rejecting claims 1-48 and 50-51 for lack of enablement, applicants appeal. Affirmed and part and reversed in part; Mayer, J., dissents with opinion.

Attorneys:

Ian C. McLeod, Okemos, Mich., for appellant.

Teddy S. Gron, associate solicitor (Fred E. McKelvey, solicitor and Richard E. Schafer, associate solicitor, with him on brief), for appellee.

Judge:

Before Rich, Archer, and Mayer, circuit judges.

Opinion Text

Opinion By:

Rich, J.

This appeal is from the September 12, 1990 decision of the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board), affirming the examiner's rejection of claims 1-48 and 50-52 of application Serial No. 07/021,405, filed March 4, 1987, titled "Hybrid Genes Incorporating a DNA Fragment Containing a Gene Coding for an Insecticidal Protein, Plasmids, Transformed Cyanobacteria Expressing Such Protein and Method for Use as a Biocontrol Agent" as unpatentable under 35 USC 103, as well as the rejection of claims 1-48 and 50-51 under 35 USC 112, first paragraph, for lack of enablement. We reverse the § 103 rejection. The § 112 rejection is affirmed in part and reversed in part.

BACKGROUND

A. The Invention

The claimed invention is directed to the use of genetic engineering techniques 1 for production of proteins that are toxic to insects such as larvae of mosquitos and black flies. These swamp-dwelling pests are the source of numerous human health problems, including malaria. It is known that certain species of the naturally-occurring *Bacillus* genus of bacteria produce proteins ("endotoxins") that are toxic to these insects. Prior art methods of combatting the insects involved spreading or spraying crystalline spores of the insecticidal *Bacillus* proteins over swamps. The spores were environmentally unstable, however, and would often sink to the bottom of a swamp before being consumed, thus rendering this method prohibitively expensive. Hence the need for a lower-cost method of producing the insecticidal *Bacillus* proteins in high volume, with application in a more stable vehicle.

As described by appellants, the claimed subject matter meets this need by providing for the production of the insecticidal *Bacillus* proteins within host cyanobacteria. Although both cyanobacteria and bacteria are members of the procaryote 2 kingdom, the

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cyanobacteria (which in the past have been referred to as "blue-green algae") are unique among procaryotes in that the cyanobacteria are capable of oxygenic photosynthesis. The cyanobacteria grow on top of swamps where they are consumed by mosquitos and black flies. Thus, when *Bacillus* proteins are produced within transformed 3 cyanobacterial hosts according to the claimed invention, the presence of the insecticide in the food of the targeted insects advantageously guarantees direct uptake by the insects.

More particularly, the subject matter of the application on appeal includes a chimeric (i.e., hybrid) gene comprising (1) a gene derived from a bacterium of the *Bacillus* genus whose product is an insecticidal protein, united with (2) a DNA promoter effective for expressing 4 the *Bacillus* gene in a host cyanobacterium, so as to produce the desired insecticidal protein.

The claims on appeal are 1-48 and 50-52, all claims remaining in the application. Claim 1 reads:

1. A chimeric gene capable of being expressed in Cyanobacteria cells comprising:

(a) a DNA fragment comprising a promoter region which is effective for expression of a DNA fragment in a Cyanobacterium; and

(b) at least one DNA fragment coding for an insecticidally active protein produced by a *Bacillus* strain, or coding for an insecticidally active truncated form of the above protein or coding for a protein having substantial sequence homology to the active protein,

the DNA fragments being linked so that the gene is expressed.

Claims 2-15, which depend from claim 1, recite preferred *Bacillus* species, promoters, and selectable markers. 5 Independent claim 16 and claims 17-31 which depend therefrom are directed to a hybrid plasmid vector which includes the chimeric gene of claim 1. Claim 32 recites a bacterial strain. Independent claim 33 and claims 34-48 which depend therefrom recite a cyanobacterium which expresses the chimeric gene of claim 1. Claims 50-51 recite an insecticidal composition. Claim 52 recites a particular plasmid that appellants have deposited.

B. Appellants' Disclosure

In addition to describing the claimed invention in generic terms, appellants' specification discloses two particular species of *Bacillus* (*B. thuringiensis*, *B. sphaericus*) as sources of insecticidal protein; and nine genera of cyanobacteria (*Synechocystis*, *Anacystis*, *Synechococcus*, *Agmenellum*, *Aphanocapsa*, *Gloecapsa*, *Nostoc*, *Anabaena* and *Ffremyllia*) as useful hosts.

The working examples relevant to the claims on appeal detail the transformation of a single strain of cyanobacteria, i.e., *Synechocystis* 6803. In one example, *Synechocystis* 6803 cells are transformed with a plasmid comprising (1) a gene encoding a particular insecticidal protein ("B.t. 8") from *Bacillus thuringiensis* var. *israelensis*, linked to (2) a particular promoter, the P_L promoter from the bacteriophage Lambda (a virus of *E. coli*). In another example, a different promoter, i.e., the *Synechocystis* 6803 promoter for the rubisco operon, is utilized instead of the Lambda P_L promoter.

C. The Prior Art

A total of eleven prior art references were cited and applied, in various combinations, against the claims on appeal.

The focus of Dzelzkalns, 6 the primary reference cited against all of the rejected claims, is to determine whether chloroplast promoter sequences can function in cyanobacteria. To that end Dzelzkalns discloses the expression in cyanobacteria of a chimeric gene comprising a chloroplast promoter sequence fused to a gene encoding the enzyme chloramphenicol acetyl transferase (CAT). 7 Importantly, Dzelzkalns teaches the use of the CAT gene as a "marker" gene; this use of antibiotic resistance-conferring genes for selection purposes is a common technique in genetic engineering.

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Sekar I, 8 Sekar II, 9 and Ganesan 10 collectively disclose expression of genes encoding certain *Bacillus* insecticidal proteins in the bacterial hosts *B. megaterium*, *B. subtilis* and *E. coli*.

Friedberg 11 discloses the transformation of the cyanobacterium *Anacystis nidulans* R2 by a plasmid vector comprising the O_LP_L operator-promoter region and a temperature-sensitive repressor gene of the bacteriophage Lambda. While the cyanobacteria are attractive organisms for the cloning of genes involved in photosynthesis, Friedberg states, problems may still be encountered such as suboptimal expression of the cloned gene, detrimental effects on cell growth of overexpressed,

highly hydrophobic proteins, and rapid turnover of some gene products. To address these problems, Friedberg teaches the use of the disclosed Lambda regulatory signals in plasmid vehicles which, it states, have "considerable potential for use as vectors the expression of which can be controlled in *Anacystis*"

Miller 12 compares the initiation specificities *in vitro* of DNA-dependent RNA polymerases 13 purified from two different species of cyanobacteria (*Freymyella diplosiphon* and *Anacystis nidulans*), as well as from *E. coli*.

Nierzwicki-Bauer 14 identifies in the cyanobacterium *Anabaena* 7120 the start site for transcription of the gene encoding *rbc* L, the large subunit of the enzyme ribulose-1, 5-bisphosphate carboxylase. It reports that the nucleotide sequence 14-8 base pairs preceding the transcription start site "resembles a good *Escherichia coli* promoter," but that the sequence 35 base pairs before the start site does not.

Chauvat 15 discloses host-vector systems for gene cloning in the cyanobacterium *Synechocystis* 6803, in which the antibiotic resistance-conferring *neo* gene is utilized as a selectable marker.

Reiss 16 studies expression in *E. coli* of various proteins formed by fusion of certain foreign DNA sequences with the *neo* gene.

Kolowsky 17 discloses chimeric plasmids designed for transformation of the cyanobacterium *Synechococcus* R2, comprising an antibiotic-resistant gene linked to chromosomal DNA from the *Synechococcus* cyanobacterium.

Barnes, United States Patent No. 4,695,455, is directed to the treatment with stabilizing chemical reagents of pesticides produced by expression of heterologous genes (such as those encoding *Bacillus* proteins) in host microbial cells such as *Pseudomonas* bacteria. The host cells are killed by this treatment, but the resulting pesticidal compositions exhibit prolonged toxic activity when exposed to the environment of target pests.

D. The Grounds of Rejection

1. The § 103 Rejections

Claims 1-6, 16-21, 33-38, 47-48 and 52 (which include all independent claims in the application) were rejected as unpatentable under 35 USC 103 based upon Dzelzkalns in view of Sekar I or Sekar II and Ganesan. The examiner stated that Dzelzkalns discloses a chimeric gene capable of being highly expressed in a cyanobacterium, said gene comprising a promoter region effective for expression in a cyanobacterium operably linked to a structural gene encoding CAT. The examiner acknowledged that the chimeric gene and transformed host of Dzelzkalns differ from the claimed invention in that the former's structural gene encodes CAT rather than insecticidally active protein. However, the examiner pointed out, Sekar I, Sekar II, and Ganesan teach genes encoding insecticidally active proteins produced by *Bacillus*, and the advantages of expressing such genes in heterologous 18 hosts to obtain larger quantities of the protein. The examiner contended that it would have been obvious to one of ordinary skill in the art to substitute the *Bacillus* genes taught by Sekar I, Sekar II, and Ganesan for the CAT gene in the vectors of Dzelzkalns in order to obtain high level expression of the *Bacillus* genes in the transformed cyanobacteria. The examiner further contended that it would have been obvious to use cyanobacteria as heterologous hosts for expression of the claimed genes due to the ability of cyanobacteria to serve as transformed hosts for the

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expression of heterologous genes. In the absence of evidence to the contrary, the examiner contended, the invention as a whole was *prima facie* obvious.

Additional rejections were entered against various groups of dependent claims which we need not address here. All additional rejections were made in view of Dzelzkalns in combination with Sekar I, Sekar II, and Ganesan, and further in view of other references discussed in Part C above.

The Board affirmed the § 103 rejections, basically adopting the examiner's Answer as its opinion while adding a few comments. The legal conclusion of obviousness does not require absolute certainty, the Board added, but only a reasonable expectation of success, citing *In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988). In view of the disclosures of the prior art, the Board concluded, one of ordinary skill in the art would have been motivated by a reasonable expectation of success to make the substitution suggested by the examiner.

2. The § 112 Rejection

The examiner also rejected claims 1-48 and 50-51 under 35 USC 112, first paragraph, on the ground that the disclosure was enabling only for claims limited in accordance with the specification as filed. Citing *Manual of Patent Examining Procedure* (MPEP) provisions 706.03(n) 19 and (z) 20 as support, the examiner took the position that undue experimentation would be required of the art worker to practice the claimed invention, in view of the unpredictability in the art, the breadth of the claims, the limited number of working examples and the limited guidance provided in the specification. With respect to unpredictability, the examiner stated that

he cyanobacteria comprise a large and diverse group of photosynthetic bacteria including large numbers of species in some 150 different genera including *Synechocystis*, *Anacystis*, *Synechococcus*, *Agmenellum*, *Nostoc*, *Anabaena*, etc. The molecular biology of these organisms has only recently become the subject of intensive investigation and this work is limited to a few genera. Therefore the level of unpredictability regarding heterologous gene expression in this large, diverse and relatively poorly studied group of procaryotes is high....

The Board affirmed, noting that "the limited guidance in the specification, considered in light of the relatively high degree of unpredictability in this particular art, would not have enabled one having ordinary skill in the art to practice the broad scope of the claimed invention without undue experimentation. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970)."

OPINION

A. Obviousness

We first address whether the PTO erred in rejecting the claims on appeal as prima facie obvious within the meaning of 35 USC 103. Obviousness is a legal question which this court independently reviews, though based upon underlying factual findings which we review under the clearly erroneous standard. *In re Woodruff*, 919 F.2d 1575, 1577, 16 USPQ2d 1934, 1935 (Fed. Cir. 1990).

[1] Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. See *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. *Id.*

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[2] We agree with appellants that the PTO has not established the prima facie obviousness of the claimed subject matter. The prior art simply does not disclose or suggest the expression in

cyanobacteria of a chimeric gene encoding an insecticidally active protein, or convey to those of ordinary skill a reasonable expectation of success in doing so. More particularly, there is no suggestion in Dzelzkalns, the primary reference cited against all claims, of substituting in the disclosed plasmid a structural gene encoding *Bacillus* insecticidal proteins for the CAT gene utilized for selection purposes. The expression of antibiotic resistance-conferring genes in cyanobacteria, without more, does not render obvious the expression of unrelated genes in cyanobacteria for unrelated purposes.

The PTO argues that the substitution of insecticidal *Bacillus* genes for CAT marker genes in cyanobacteria is suggested by the secondary references Sekar I, Sekar II, and Ganesan, which collectively disclose expression of genes encoding *Bacillus* insecticidal proteins in two species of host *Bacillus* bacteria (*B. megaterium* and *B. subtilis*) as well as in the bacterium *E. coli*. While these references disclose expression of *Bacillus* genes encoding insecticidal proteins in certain transformed bacterial hosts, nowhere do these references disclose or suggest expression of such genes in transformed cyanobacterial hosts.

To remedy this deficiency, the PTO emphasizes similarity between bacteria and cyanobacteria, namely, that these are both procaryotic organisms, and argues that this fact would suggest to those of ordinary skill the use of cyanobacteria as hosts for expression of the claimed chimeric genes. While it is true that bacteria and cyanobacteria are now both classified as procaryotes, that fact alone is not sufficient to motivate the art worker as the PTO contends. As the PTO concedes, cyanobacteria and bacteria are not identical; they are classified as two separate divisions of the kingdom Procaryotae. ²¹ Moreover, it is only in recent years that the biology of cyanobacteria has been clarified, as evidenced by references in the prior art to "blue-green algae." Such evidence of recent uncertainty regarding the biology of cyanobacteria tends to rebut, rather than support, the PTO's position that one would consider the cyanobacteria effectively interchangeable with bacteria as hosts for expression of the claimed gene.

At oral argument the PTO referred to additional secondary references, not cited against any independent claim (i.e., Friedberg, Miller, and Nierzwicki-Bauer), which it contended disclose certain amino acid sequence homology between bacteria and cyanobacteria. The PTO argued that such homology is a further suggestion to one of ordinary skill to attempt the claimed invention. We disagree. As with the Dzelzkalns, Sekar I, Sekar II, and Ganesan references discussed above, none of these additional references disclose or suggest that cyanobacteria could serve as hosts for expression of genes encoding *Bacillus* insecticidal proteins. In fact, these additional references suggest as much about *differences* between cyanobacteria and bacteria as they do about similarities. For example, Nierzwicki-Bauer reports that a certain nucleotide sequence (i.e., the -10 consensus sequence) in a particular cyanobacterium resembles an *E. coli* promoter, but that another nearby nucleotide sequence (the -35 region) does not. While Miller speaks of certain promoters of the bacteriophage Lambda that are recognized by both cyanobacterial and *E. coli* RNA polymerases, it also discloses that these promoters exhibited differing strengths when exposed to the different polymerases. Differing sensitivities of the respective polymerases to an inhibitor are also disclosed, suggesting differences in the structures of the initiation complexes.

The PTO asks us to agree that the prior art would lead those of ordinary skill to conclude that cyanobacteria are attractive hosts for expression of any and all heterologous genes. Again, we can not. The relevant prior art does indicate that cyanobacteria are attractive hosts for expression of both native and heterologous genes involved in photosynthesis (not surprisingly, for the capability of undergoing oxygenic photosynthesis is what makes the cyanobacteria unique among procaryotes). However, these references do not suggest that cyanobacteria would be equally attractive hosts for expression of *unrelated* heterologous genes, such as the claimed genes encoding *Bacillus* insecticidal proteins.

In *O'Farrell*, this court affirmed an obviousness rejection of a claim to a method for

producing a "predetermined protein in a stable form" in a transformed bacterial host. 853 F.2d at 895, 7 USPQ2d at 1674. The cited references included a prior art publication (the Polisky reference) whose three authors included two of the three coinventor-appellants. The main difference between the prior art and the claim at issue was that in Polisky, the heterologous gene was a gene for ribosomal RNA, while the claimed invention substituted a gene coding for a predetermined protein. *Id.* at 901, 7 USPQ2d at 1679. Although, as the appellants therein pointed out, the ribosomal RNA gene is not normally translated into protein, Polisky mentioned preliminary evidence that the transcript of the ribosomal RNA gene was translated into protein, and further predicted that if a gene coding for a protein were to be substituted, extensive translation might result. *Id.* We thus affirmed, explaining that

the prior art explicitly suggested the substitution that is the difference between the claimed invention and the prior art, and presented preliminary evidence suggesting that the [claimed] method could be used to make proteins.

....

... Polisky contained detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful.

Id. at 901-02, 7 USPQ2d at 1679-80.

In contrast with the situation in *O'Farrell*, the prior art in this case offers no suggestion, explicit or implicit, of the substitution that is the difference between the claimed invention and the prior art. Moreover, the "reasonable expectation of success" that was present in *O'Farrell* is not present here. Accordingly, we reverse the § 103 rejections.

B. Enablement

[3] The first paragraph of 35 USC 112 requires, *inter alia*, that the specification of a patent enable any person skilled in the art to which it pertains to make and use the claimed invention. Although the statute does not say so, enablement requires that the specification teach those in the art to make and use the invention without "undue experimentation." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). That *some* experimentation may be required is not fatal; the issue is whether the amount of experimentation required is "undue." *Id.* at 736-37, 8 USPQ2d at 1404. Enablement, like obviousness, is a question of law which we independently review, although based upon underlying factual findings which we review for clear error. *See id.* at 735, 8 USPQ2d at 1402.

In response to the § 112 rejection, appellants assert that their invention is "pioneering," and that this should entitle them to claims of broad scope. Narrower claims would provide no real protection, appellants argue, because the level of skill in this art is so high, art workers could easily avoid the claims. Given the disclosure in their specification, appellants contend that any skilled microbiologist could construct vectors and transform many different cyanobacteria, using a variety of promoters and *Bacillus* DNA, and could easily determine whether or not the active *Bacillus* protein was successfully expressed by the cyanobacteria.

The PTO made no finding on whether the claimed invention is indeed "pioneering," and we need not address the issue here. With the exception of claims 47 and 48, the claims rejected under § 112 are not limited to any particular genus or species of cyanobacteria. The PTO's position is that the cyanobacteria are a diverse and relatively poorly studied group of organisms, comprising some 150 different genera, and that heterologous gene expression in cyanobacteria is "unpredictable." Appellants have not effectively disputed these assertions. Moreover, we note that only one particular species of cyanobacteria is employed in the working examples of appellants' specification, and only nine genera of cyanobacteria are mentioned in the entire document.

[4] Taking into account the relatively incomplete understanding of the biology of cyanobacteria as of appellants' filing date, as well as the limited disclosure by appellants of particular cyanobacterial genera operative in the claimed invention, we are not persuaded that the PTO erred in rejecting claims 1-46 and 50-51 under § 112, first paragraph. There is no reasonable correlation between the narrow disclosure in appellants' specification and the broad scope of protection sought in the claims encompassing gene expression in any and all cyanobacteria. *See In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (the first paragraph of § 112 requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification).

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22 Accordingly, we affirm the § 112 rejection as to those claims.

In so doing we do *not* imply that patent applicants in art areas currently denominated as "unpredictable" must never be allowed generic claims encompassing more than the particular species disclosed in their specification. It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Angstadt*, 537 F.2d 498, 502-03, 190 USPQ 214, 218 (CCPA 1976). However, there must be sufficient disclosure, either through illustrative examples or terminology, 23 to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility. Where, as here, a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than, for example, the disclosure of an invention involving a "predictable" factor such as a mechanical or electrical element. *See Fisher*, 427 F.2d at 839, 166 USPQ at 24. In this case, we agree with the PTO that appellants' limited disclosure does not enable one of ordinary skill to make and use the invention as now recited in claims 1-46 and 50-51 without undue experimentation.

Remaining dependent claim 47 recites a cyanobacterium which expresses the chimeric gene of claim 1, wherein the cyanobacterium is selected from among the genera *Anacystis* and *Synechocystis*. Claim 48, which depend from claim 47, is limited to the cyanobacterium *Synechocystis* 6803. The PTO did not separately address these claims, nor indicate why they should be treated in the same manner as the claims encompassing all types of cyanobacteria. Although these claims are not limited to expression of genes encoding particular *Bacillus* proteins, we note what appears to be an extensive understanding in the prior art of the numerous *Bacillus* proteins having toxicity to various insects. The rejection of claims 47-48 under § 112 will not be sustained.

CONCLUSION

The rejection of claims 1-48 and 50-52 under 35 USC 103 is *reversed*. The rejection of claims 1-46 and 50-51 under 35 USC 112, first paragraph, is *affirmed* and the rejection of claims 47 and 48 thereunder is *reversed*.

AFFIRMED-IN-PART, REVERSED-IN-PART

Footnotes

Footnote 1. Basic vocabulary and techniques for gene cloning and expression have been described in *In re O'Farrell*, 853 F.2d 894, 895-99, 7 USPQ2d 1673, 1674-77 (Fed. Cir. 1988), and are not repeated here.

Footnote 2. All living cells can be classified into one of two broad groups, procaryotes and

eucaryotes. The procaryotes comprise organisms formed of cells that do not have a distinct nucleus; their DNA floats throughout the cellular cytoplasm. In contrast, the cells of eucaryotic organisms such as man, other animals, plants, protozoa, algae and yeast have a distinct nucleus wherein their DNA resides.

Footnote 3. "Transformed" cyanobacteria are those that have successfully taken up the foreign *Bacillus* DNA such that the DNA information has become a permanent part of the host cyanobacteria, to be replicated as new cyanobacteria are generated.

Footnote 4. "Expression" of a gene refers to the production of the protein which the gene encodes; more specifically, it is the process of transferring information from a gene (which consists of DNA) via messenger RNA to ribosomes where a specific protein is made.

Footnote 5. In the context of the claimed invention, "selectable markers" or "marker genes" refer to antibiotic-resistance conferring DNA fragments, attached to the gene being expressed, which facilitate the selection of successfully transformed cyanobacteria.

Footnote 6. *Nucleic Acids Res.* 8917 (1984).

Footnote 7. Chloramphenicol is an antibiotic; CAT is an enzyme which destroys chloramphenicol and thus imparts resistance thereto.

Footnote 8. *Biochem. and Biophys. Res. Comm.* 748 (1986).

Footnote 9. *Gene* 151 (1985).

Footnote 10. *Mol. Gen. Genet.* 181 (1983).

Footnote 11. *Mol. Gen. Genet.* 505 (1986).

Footnote 12. *J. Bacteriology* 246 (1979).

Footnote 13. RNA polymerase, the enzyme responsible for making RNA from DNA, binds at specific nucleotide sequences (promoters) in front of genes in DNA, and then moves through the gene making an RNA molecule that includes the information contained in the gene. Initiation specificity is the ability of the RNA polymerase to initiate this process specifically at a site(s) on the DNA template.

Footnote 14. *Proc. Natl. Acad. Sci. USA* 5961 (1984).

Footnote 15. *Mol. Gen. Genet.* 185 (1986).

Footnote 16. *Gene* 211 (1984).

Footnote 17. *Gene* 289 (1984).

Footnote 18. Denotes different species or organism.

Footnote 19. MPEP 706.03(n), "Correspondence of Claim and Disclosure," provides in part:

In chemical cases, a claim may be so broad as to not be supported by [the] disclosure, in which case it is rejected as unwarranted by the disclosure....

Footnote 20. MPEP 796.03(z), "Undue Breadth," provides in part:

n applications directed to intentions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Sol*, 1938 C.D. 723; 497 O.G. 546. This is because in arts such as chemistry it is not obvious from the

disclosure of one species, what other species will work. *In re Dreshfield*, 1940 C.D. 351; 518 O.G. 255 gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." ...

Footnote 21. *Stedman's Medical Dictionary* 1139 (24th ed. 1982) (definition of "Procaryotae"). Procaryotic organisms are commonly classified according to the following taxonomic hierarchy: Kingdom; Division; Class; Order; Family; Genus; Species. 3 *Bergey's Manual of Systematic Bacteriology* 1601 (1989).

Footnote 22. The enablement rejection in this case was not based upon a post-filing date state of the art, as in *In re Hogan*, 559 F.2d 595, 605-07, 194 USPQ 527, 536-38 (CCPA 1977). See also *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 USPQ2d 1461, 1464 (Fed. Cir. 1989) (citing *Hogan*); *Hormone Research Found., Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1568-69, 15 USPQ2d 1039, 1047-48 (Fed. Cir. 1990) (directing district court, on remand, to consider effect of *Hogan* and *United States Steel* on the enablement analysis of *Fisher*), *cert. dismissed*, — U.S. —, 111 S. Ct. 1434 (1991). We therefore do not consider the effect of *Hogan* and its progeny on *Fisher*'s analysis of when an inventor should be allowed to "dominate the future patentable inventions of others." *Fisher*, 427 F.2d at 839, 166 USPQ at 24.

Footnote 23. The first paragraph of § 112 requires nothing more than *objective* enablement. *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is irrelevant. *Id.*

Dissenting Opinion Text

Dissent By:

Mayer, J., dissenting.

An appeal is not a second opportunity to try a case or prosecute a patent application, and we should not allow parties to "undertake to retry the entire case on appeal." *Perini America, Inc. v. Paper Converting Machine Co.*, 832 F.2d 581, 584, 4 USPQ2d 1621, 1624 (Fed. Cir. 1987); *Eaton Corp. v. Appliance Valves Corp.*, 790 F.2d 874, 877, 229 USPQ 668, 671 (Fed. Cir. 1986). But that is precisely what the court has permitted here. The PTO conducted a thorough examination of the prior art surrounding this patent application and concluded the claims would have been obvious. The board's decision based on the examiner's answer which comprehensively explains the rejection is persuasive and shows how the evidence supports the legal conclusion that the claims would have been obvious. Yet, the court ignores all this and conducts its own examination, if you will, as though the examiner and board did not exist. Even if thought this opinion were more persuasive than the board's, I could not join it because it misperceives the role of the court.

The scope and content of the prior art, the similarity between the prior art and the claims, the level of ordinary skill in the art, and what the prior art teaches are all questions of fact. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966); *Jurgens v. McKasy*, 927 F.2d 1552, 1560, 18 USPQ2d 1031, 1037 (Fed. Cir. 1991). And "[w]here there are two permissible views of

Page 1446

the evidence, the factfinder's choice between them cannot be clearly erroneous." *Anderson v. City of Bessemer City*, 470 U.S. 564, 574 (1985). The mere denomination of obviousness as a question of law does not give the court license to decide the factual matters afresh and ignore the requirement that they be respected unless clearly erroneous. *In re Woodruff*, 919 F.2d 1575, 1577, 16 USPQ2d 1934, 1935 (Fed. Cir. 1990); *In re Kulling*, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1057 (Fed. Cir.

1990). There may be more than one way to look at the prior art, but on this record we are bound by the PTO's interpretation of the evidence because it is not clearly erroneous and its conclusion is unassailable. I would affirm on that basis.

- End of Case -

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FULL TEXT OF CASES (USPQ FIRST SERIES)**Ex parte Clapp, 227 USPQ 972 (BdPatApp&Int 1985)**

Ex parte Clapp, 227 USPQ 972 (BdPatApp&Int 1985)

Ex parte Clapp**(BdPatApp&Int)
227 USPQ 972****Opinion dated Feb. 28, 1985****U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences****Headnotes****PATENTS****1. Anticipation -- Combining references -- (§ 51.205)**

To support conclusion that claimed combination is directed to obvious subject matter, references must either expressly or impliedly suggest claimed combination or examiner must present convincing line of reasoning as to why artisan would have found claimed invention to have been obvious in light of references' teachings.

Case History and Disposition:

Page 972

Application for patent of ThomasR. Clapp, Serial No. 257,162, filed Apr. 24, 1981. From rejection of Claim 9-19, applicant appeals (Appeal No. 553-54). Reversed.

Attorneys:

Gomer W. Walters, for appellant.

Judge:

Before Bennett, Henon and Spencer, Examiners-in-

Opinion Text**Opinion By:**

Henon, Examiner-in-Chief.

This appeal is from the decision of the examiner rejecting claims 9 through 19, which constitute all the claims remaining in the application.

The invention relates to an auger type mixing apparatus for mixing cementitious materials

employing a volatile liquid. Representative claim 9 reads as follows:

9. Apparatus mounted on a vehicle for mixing a cementitious material in which a volatile liquid is employed comprising:

an enclosed mixing chamber sealed to prevent the escape of the volatile liquid and any potentially dangerous fumes;

a solid frame forming the top of said mixing chamber and having an inlet end thereof pivotably mounted on the vehicle;

an easily removable elastomeric trough forming the bottom of said mixing chamber, the elastomeric material selected to be compatible with the materials being mixed;

an auger having a central shaft and mounted in said frame to convey materials through said mixing chamber;

mixing paddles mounted on the shaft of said auger;

a drive motor for said auger mounted on said frame;

a releasable flexible coupling between the aligned shafts of said motor and said auger to permit removal of said auger from said frame;

an inlet hopper to introduce substantially dry materials into said mixing chamber;

liquid injection means to introduce a liquid into said mixing chamber at a distance removed from said inlet hopper to have said substantially dry material form a plug to prevent the liquid and any fumes from backing up said inlet hopper; and

a discharge opening formed in said elastomeric trough.

The references relied on by the examiner are:

Table set at this point is not available. See table in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

FULL TEXT OF CASES (USPQ FIRST SERIES)

In re Aller, Lacey, and Hall, 105 USPQ 233 (CCPA 1955)

In re Aller, Lacey, and Hall, 105 USPQ 233 (CCPA 1955)

In re Aller, Lacey, and Hall

(CCPA)

105 USPQ 233

Decided Mar. 22, 1955

Appl. No. 6079

U.S. Court of Customs and Patent Appeals

Headnotes



1. Patentability-Change-In general (§ 51.251)

Patentability-Change - Proportions (§ 51.259)

Normally, change in temperature, concentration, or both, is not patentable modification; however, such changes may impart patentability to process if ranges claimed produce new and unexpected result which is different in kind and not merely in degree from results of prior art; such ranges are termed "critical" ranges, and applicant has burden of proving such criticality; even though applicant's modification results in great improvement and utility over prior art, it may still not be patentable if modification was within capabilities of one skilled in art; more particularly, where general conditions of claim are disclosed in prior art, it is not inventive to discover optimum or workable ranges by routine experimentation.

2. Patentability-Evidence of-Commercial success-Doubtful cases (§ 51.4557)

Commercial success or improved results are important only when question of invention is in doubt; where there is no doubt that improvement resulted from routine efforts of artisan, commercial utility is unimportant.

3. Patentability-Invention-In general (§ 51.501)

To support patent, it must be shown that claimed process was not obvious to one skilled in art, who had prior art article before him.

4. Patentability-Anticipation-In general (§ 51.201)

References are valid for what they convey, explicitly or implicitly, to one skilled in art; that experimentation may not have appeared promising is of no importance; reference may be valid even

though it states that its disclosure is not practical.

Particular patents-Organic Peroxides

Aller, Lacey, and Hall, Decomposition of Organic Peroxides, claims 1 to 10, 15, and 16 of application refused.

Case History and Disposition:

Page 234

Appeal from Board of Appeals of the Patent Office.

Application for patent of Basil Vivian Aller, Richard Norman Lacey, and Reginald Harold Hall, Serial No. 45,326, filed Aug. 20, 1948; Patent Office Division 31. From decision rejecting claims 1 to 10, 15, and 16, applicants appeal. Affirmed.

Attorneys:

Clinton F. Miller, Wilmington, Del., for appellants.

E. L. Reynolds (J. Schimmel of counsel) for Commissioner of Patents.

Judge:

Before Garrett, Chief Judge, and O'Connell, Johnson, Worley and Cole, Associate Judges.

Opinion Text

Opinion By:

Cole, Judge.

This is an appeal from a decision of the Board of Appeals of the United States Patent Office, affirming the rejection by the Primary Examiner of appellants' application for a patent, Serial No. 45,326, filed August 20, 1948, for "Decomposition of Organic Peroxides." Of the original sixteen claims, claims 11-14 have been withdrawn, and no claims have been allowed, all having been denied as unpatentable over a reference specifically acknowledged in the application as prior art, as hereinafter discussed.

The rejection was made upon an article appearing in the Journal of the German Chemical Society in 1944, by Heinrich Hock and Shon Lang, entitled, "Autoxidation of hydrocarbons, Report no. 9: Concerning peroxides of benzene derivatives." The reference is cited as follows:

Hock et al. Ber. Deut. Chem. Ges., 77B, pages 257 to 262,

The application is for a process for the production of phenol (carbolic acid), a chemical with wide uses as an antiseptic and preservative, and as an ingredient in the production of synthetic resins, explosives, drugs, photographic developers, and dyes. Ketones (particularly acetone) are produced as by-products of the process.

Basically, the process sought to be patented involves the treatment of isopropyl benzene hydroperoxide (or similar organic peroxides) with sulphuric acid, wherein the hydroperoxide is

decomposed into phenol and acetone (or other ketones). So far as pertinent to this appeal, it is not necessary to inquire into the particular chemical reactions occurring in the process, nor is it necessary to discuss the method by which isopropyl benzene hydroperoxide is formed.

The process of appellants is identical with that of the prior art, except that appellants' claims specify lower temperatures and higher sulphuric acid concentrations than are shown in the reference. (Some of the claims also specify the use of solvents, but these are better discussed separately.) The main question involved in this appeal is whether the changes in temperature and in acid concentration amount to invention, or whether such changes would have been obvious to one skilled in the art.

Claim 8 was quoted by the Board of Appeals as illustrative, and reads as follows:

8. Process for decomposing isopropyl benzene hydroperoxide and the production thereby of phenol and acetone which comprises bringing said peroxides into intimate contact with aqueous sulphuric acid of a concentration between 25 and 70% at temperatures between 40° and 80°.

The reference article shows essentially the same process as that recited in the claims, except that the only experiment discussed in the article was conducted at a temperature of 100° C. and with a 10% sulphuric acid solution. ¹

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The Primary Examiner held that the conditions of the claims resulted simply from experimentally varying the different factors of the process to determine the optimum reaction condition and was within the skill of the art; that there was no evidence to indicate that the reported increase in yields was a difference in kind and not of degree; that no actual commercial success had been shown; that even if commercial success had been shown, it would be insufficient of itself to show invention; and that quickened reaction times were not pertinent to show invention.

The Board of Appeals, in affirming the examiner, stated that experimentation to find the optimum conditions of temperatures and acid concentration was "no more than the application of the expected skill of the chemical engineer * * *." The board stated that the record did not show any significant improvement in the efficiency of the process resulting from a difference in temperature, and that the essential question was whether an increase of concentration of acid which resulted in an increase in yield was a difference of degree only, or whether it was a "difference of such magnitude as to justify the allowance of the claims." The board held that the record failed to support a holding that there was patentable invention. An affidavit submitted by appellants after the examiner's rejection in an attempt to prove that the claimed process was "commercially attractive" while that of the reference was not, was accepted by the board only as further argumentation, and not as evidence.

[1] Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. In re Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931, 24 USPQ 52 ; In re Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. In re Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372 ; In re Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. In re Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433 ; In re Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308 ; In re Irmischer, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314 . More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or

workable ranges by routine experimentation. In re Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136.

Bearing in mind the foregoing, we examine the arguments of appellants to determine whether they have demonstrated patentability over the experiment of Hock and Lang.

Appellants specify three improved results from the conditions of the process sought to be patented; increased yields of phenol; increased yields of acetone; and shortened reaction times. These results, it is claimed, combine to make appellants' process commercially attractive while that of the reference would be commercially unattractive.

The yield of phenol reported by the reference article was 75% of theoretical, whereas the examples of appellants' specification show phenol yields of 83.7 to 100%. The reference did not state what acetone yield Hock and Lang obtained, although it did indicate that acetone was produced. Appellants' specification states that in following the conditions of the reference they obtained an acetone yield of about 60%. By their own method, appellants report acetone yields of from 71 to 88%, the yield, however, not being reported for two examples. The Hock and Lang reference experiment was completed in an hour and a half. Appellants' examples show comparable reaction times ranging from a total time of 20 minutes to three hours.

In analyzing these improved results, one is not struck by any difference in *kind* attributable to appellants' process-logically the improvements could flow equally well from changes in *degree* resulting from routine variation in temperature or acid concentration. At the least efficient conditions reported by ap

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pellants, the improvement is but a few percentage points different from the results reported by the reference. At the most efficient conditions, the improvement is still within the range of variation one might expect to result from changes in reaction conditions. There is no temperature range or acid concentration range that can really be termed "critical." As far as is shown, temperatures between 80° and 100° C., and acid concentrations between 10% and 25%, could result in increasingly greater efficiency, somewhat more than Hock and Lang, somewhat less than appellants. Appellants have not shown anything "critical" about their process, unless lower temperatures and higher acidity generally are critical.

Even the affidavit of Sheffield does little more than compare the results reported by the reference and those reported by appellants, and give an opinion as to how much less costly one would be than the other. The affidavit clearly does not show commercial success. It only presents affiant's opinion that when the price of phenol is 19 cents a pound, appellants' production would be economically profitable, while that of the reference would not. His statement is equally compatible with the theory that the improvement is a difference of degree, as it is with the theory that it is a difference of kind.

[2] However, for purposes of discussion, it may be assumed that appellants have shown an improvement over the reference, and that commercial success has been adequately demonstrated. Commercial success or improved results, however, are important only when the question of invention is in doubt. When there is no doubt that improvement resulted from routine efforts of the artisan, then commercial utility is unimportant. To

[3] support a patent, it must be shown that the claimed process was not obvious to one skilled in the art, who had before him the Hock and Lang article.

Appellants contend that the claimed conditions would not be discovered by one skilled in the art, because shortened reaction times would not be expected with lower temperatures; increased resinification (and hence lower yields) of phenol and acetone would be expected with stronger acids;

and greater danger of explosion would be expected at lower temperatures.

In support of the first argument, appellants state that theoretically reaction time is doubled or trebled for each 10°C. drop in temperature, while it is only shortened proportionately with an increase in the concentration of a reactant. Hence, it is argued that a skilled chemist would expect the reaction time to be inordinately lengthened by a decrease in temperature, despite an increase in the concentration of the sulphuric acid. Assuming appellants' propositions to be applicable, it still does not follow that a skilled chemist would not try to shorten the reaction time by lowering the temperature and increasing the acid concentration. Thus, applying appellants' reasoning, at 80°C. and 70% acid concentration (which is within the limits of the claims) it would be expected that the reaction rate would be slowed at least four times by the temperature reduction-but that it would be accelerated *seven* times by the increase in acid concentration.

There is a dispute between counsel as to the validity of appellants' second assertion, that resinification should be expected with higher acid concentrations. The Solicitor for the Patent Office cited authority to show that such resinification occurs only under extreme conditions of pressure and temperature. Appellants in a reply brief give further citation to the same authority to show the conditions were not as drastic as indicated by the solicitor. However, even taking at full value all the statements of appellants, it still appears that the reaction is a slow one, taking as long as twelve hours or more for completion, and that it is affected by temperature. There is no evidence to show that a chemist should necessarily expect that an increase in acid strength would be impracticable. As far as the evidence shows, the increased resinification due to stronger acidity might be negligible in its proportions, or it might be extensive. Experimentation would be indicated to determine the exact effect.

The third argument of appellants in this regard is that a chemist would assume that the reaction would be more likely to be explosive at a lower temperature. It is stated in appellants' brief:

A final consideration and one which is most important is the safety of the process. If the reaction time of the Hock et al. process were to be lengthened as by lowering the temperature, as the hydroperoxide is added to the acid the concentration of hydroperoxide would increase due to the slowness of the decomposition process. *There would then be great danger of the reaction becoming exothermic and causing a violent explosion.* Within the limits of the appealed claims, however, the reaction may be safely carried out. [Italics quoted.]

That a reaction would be more explosive at a lower temperature goes against all common experience, and is apparently based on a gratuitous assumption that

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the hydroperoxide will be added to the reaction solution faster than it is being decomposed. Whether or not the general proposition is correct, there is insufficient proof of it in this record for us to reverse the concurring decisions of the tribunals of the Patent Office.

Upon reviewing all of the evidence in the case, it is evident that the contentions of appellants cannot be upheld. Hock and Lang disclosed generally the process of decomposition of isopropyl benzene hydroperoxide by sulphuric acid, with the production of phenol and acetone. They described one experiment and its results, indicating in no way that this was the maximum yield obtainable. Any chemist reading the article could logically assume that higher yields might be obtainable, and by experimentally varying the conditions of temperature and acidity could find the most productive conditions. If it could be held that the skilled chemist would never think to reduce the temperature or increase the acid concentration, then it might be held that invention resides in so doing. However, appellants have not demonstrated such fact. The skilled chemist who chose to experiment with the reference process would undoubtedly try the conditions defined by the claims, although he might be surprised at the extent of improvement obtained. No invention is involved in discovering optimum

ranges of a process by routine experimentation. In re Swain et al., supra.

[4] Appellants suggest that the decision to experiment with the process in the first place involves invention, apparently on the theory that the process as disclosed by Hock and Lang appeared so impractical that no skilled chemist would have experimented with it. References have always been valid for what they would convey, explicitly or implicitly, to one skilled in the art. That experimentation may not have appeared promising is of no importance. It has been held that a reference may be valid even though it states in so many words that its disclosure is not practical. In re McKee et al., 25 C.C.P.A. (Patents) 1116, 96 F.2d 504, 37 USPQ 613 ; In re Krukovsky et al., 38 C.C.P.A. (Patents) 731, 184 F.2d 333, 87 USPQ 110.

The Board of Appeals, in concluding its opinion, stated as follows:

* * * any one in possession of the information presented by Hock et al. would naturally experiment to discover optimum conditions of temperature and concentration of acid for commercial exploitation of the process. Such experimentation is no more than the application of the expected skill of the chemical engineer and failure to perform such experiments would, in our opinion, show a want of the expected skill of the engineer. * * *

That we are in complete agreement with the board's reasoning is clear from the foregoing discussion.

Some of the appealed claims, as noted above, specify the use of certain solvents in the process, in addition to the temperature and acid concentration limitations. The Primary Examiner stated that the reference showed the use of solvents, and stated that the choice of a particular solvent was within the skill of the art. The Board of Appeals affirmed this ground of rejection. Although appellants argue that this feature imparts patentability to the claims, no arguments are advanced sufficient to discredit the examiner's ruling in this respect.

It being apparent that the claimed process is merely different in degree and not in kind from the reference process, and that the criticality of the claimed ranges has not been shown, the decision of the Board of Appeals is affirmed.

Footnotes

Footnote 1. Without subscribing to the accuracy of the translation, we set forth at this point the experiment as described in the reference in the following language:

Acid cleavage: 1.2 g. isopropylbenzol peroxide were heated with 15 ccm. 10% sulfuric acid on the reflux condenser (temperature in the tube 100°, in the condenser 60°). The condenser outlet was connected with a U-tube which contained about 2 ccm. water and was cooled with ice. The reaction mixture was cooled for 1½ hours, 2 g. sodium hydroxide added and then filtered through a wet filter in doing which oily drops (presumably dimethyl - phenyl - carbinol were left behind). The filtrate was shaken with 1.5 g. of benzoyl chloride and the separated phenyl benzoate recrystallized from alcohol. Melting point 68-69°. Yield 1.15 g. (75% of the theoretical). The mixture melting point with phenyl benzoate showed no reduction.

The aqueous solution in the U. tube showed with sodium nitroprussiate on the addition of ammonia and some solid ammonium chloride a permanganese red coloring (acetone).

- End of Case -

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FULL TEXT OF CASES (USPQ FIRST SERIES)
In re Margolis, et al., 228 USPQ 940 (CA FC 1986)

In re Margolis, et al., 228 USPQ 940 (CA FC 1986)

In re Margolis, et al.

(CA FC)
228 USPQ 940

Decided March 7, 1986

No. 85-2616

U.S. Court of Appeals Federal Circuit

Headnotes**PATENTS****1. Patentability -- Aggregation or combination -- New or better result (§ 51.157)**

Patent Office erred in rejecting applicants' coffee processing claims for obviousness as based solely upon prior art, without considering, as evidence of invention's unexpected results, data in specification comparing coffee made by claimed oxygen-free process with coffee produced without removal of oxygen.

Case History and Disposition:

Appeal from Patent and Trademark Office Board of Patent Appeals and Interferences.

Application for patent of Geoffrey Margolis, Alain Mercier, and Klaus Schlecht, application, Serial No. 297,324. From decision affirming examiner's rejection of claims 1-8, applicants appeal. Vacated and remanded.

Attorneys:

William H. Vogt, III, and Vogt & O'Donnell, both of White Plains, N.Y. (Glenn E. Karta, of counsel) for appellants.

Robert D. Edmonds, Associate Solicitor (Joseph F. Nakamura, Solicitor, and Fred E. McKelvey, Deputy Solicitor, on the brief) for Patent and Trademark Office.

Judge:

Before Markey, Chief Judge, and Smith and Newman, Circuit Judges.

Opinion Text**Opinion By:**

Newman, Circuit Judge.

Margolis takes issues with the Board's reading of the specification. Margolis argues that the purpose of the specification is to describe and illustrate the claimed invention, and characterizes the Board's reading of the disclosure as "contrary to logic, reason, and the text of the specification". He points to various statements in the specification:

According to the invention the process comprises wetting, in the absence of oxygen . . .
transferring the wetted coffee, out of contact with oxygen. . . .

and immediately preceding the examples:

The following examples are given for the purposes of illustrating the process according to the invention.

[1] We agree with Margolis that the Board's position is in error. It is plain that the examples illustrate Margolis' invention.

The specific examples provided the basis for the comparative data tabulated *supra*. The Board had not commented on the probative

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value of these data, in view of its criticism of the examples. Neither had the Examiner. The data which compare the products of examples 1 and 5 with conventional instant coffee must be considered in reaching a conclusion as to whether the claimed invention as a whole would have been obvious. Neither the prior art, nor the comparative data, is properly considered alone.

It is the entire body of evidence, that arising in the prior art and that provided by the applicant, which must be weighed in the first instance by the PTO. Because the Board did not consider Margolis' comparative data, the record before us is insufficient. 35 U.S.C. §144. To enable these further proceedings before the PTO, the decision of the Board is vacated and the case is remanded.

The Commissioner in his brief presented certain new arguments on this appeal, relying on references that had been before the Examiner, but raising objections under 35 U.S.C. §102 and §103 that had not been appealed to or relied upon by the Board. In the interest of an orderly and fair administrative process, it is inappropriate for this court to consider rejections that had not been considered by or relied upon by the Board. *In re Hedges*, No. 85-2524, slip op. at 3, 228 USPQ at 685 (Fed. Cir. Feb. 12, 1986); *In re Hounsfield*, 699 F.2d 1320, 1324, 216 USPQ 1045, 1048-49 (Fed. Cir. 1983).

VACATED AND REMANDED

- End of Case -